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The AI act regulation proposal:
a European answer to AI regulation

Prof.ssa Cristina Alaimo

Supervisor

Prof. Francesco Maria Salerno

Co-supervisor

Edoardo Röhrssen di Limina - 643912

Candidate

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Introduction

Throughout history, technological evolution is what has moved forward the world, making it smarter and more efficient. Following this trend, it fits particularly well Artificial Intelligence (AI) which is a class of technologies and application that try to resemble as close as possible the human cognitive skills.

In recent years, these technologies have been implemented within business environments and organizations, with the goal of increasing production with a simultaneous decrease in costs. Although this has not been a foregone achievement for those that have employed AI, it has been remarkable the benefits that some businesses have seen with the implementation of these applications. For this reason, both private and public actors have started to invest a lot in the creation of a complete AI ecosystem to be able to rip its benefits through the spread of this technology across society.

However, this takeover has not been equal across the world. For instance, Europe and its Member States are currently lagging behind both US and China, in terms of investments and overall output. These policies choice have seen the huge boost of their AI markets, making their companies also strong global players in both developing AI solutions and in powering their businesses with these technologies.

On the contrary, Europe has had difficulties in undertaking such transformation and has not been able yet to fully untap the already present potential, in terms of competences and production power. In turn, this has led to a difficulty to innovate and European companies may find themselves blocked by foreign competitions. If this would have been possible through a sound strategy, Europe, as a great producer of goods on the global stages, would benefit greatly from AI technologies for both their production system and the goods themselves.

Furthermore, it can also become a great player in the development of AI solutions and be able to compete with foreign actors thanks to the high-quality competences already present in Europe, which are unfortunately in limited number.

However, despite having numerous advantages, AI could also generate many risks to both companies that develop and deploy such solutions, as well as citizens and society as a whole. These could range from a non-sound management of data to the problem of inherent biases into AI system, as well as manipulative practices by these systems.

However, the European Union (EU) has attempted to invert both trends. In recent years, it has deployed many resources for the development of a European AI ecosystem through the use of funds and the creation of pan-European projects. In addition, it has also pushed Member States

to act at national level in setting the proper conditions for such development through the creation of AI national strategies.

The latest attempt, in this direction, has been the AI act regulation proposal published by the European Commission on November 2021. The basis of this proposal is to set clearly defined rules for a European AI ecosystem and create a more secure and trustworthy environment for citizens and businesses with the final goal of increasing the implementation of this technology within the European single market.

To do so, it sets different restrictions on both developers and deployers of AI systems to guarantee the protection of citizens' fundamental rights, raising businesses production costs and bureaucratic constraints. Although this proposal wants to boost the AI market within Europe, this could be problematic for SMEs and startups, which have already many obstacles in the current environment due to inherent problems at national level. On a similar note, the whole innovation process could easily suffer from the increased number of conditions put in place on companies that are pioneers for an innovative development.

This research wants to analyze these topics by looking at what could be the possible impact of the AI Act regulation proposal for SMEs and startups, as well as on the overall innovation process. By doing so, it examines what the AI act proposal endorses, while pondering whether it could really be a solution for the development of the European AI ecosystem. Specifically, it seeks to investigate whether the proposal is able to protect innovation and small-scale actors through the definition of specific provisions within the proposal, such as regulatory sandboxes. To answer to such questions, this thesis is divided as follows. The first chapter will focus on AI, by looking at what is its possible definition, possible applications within a business environment and the possible sources of risks that this technology may produce on society.

The second chapter will concentrate on the European regulation proposal on AI, the so-called AI act. It will look at the main contents of the piece of legislation and its main critical points. Consequently, it will introduce the 2 main topics of this research the focus of the proposal on both innovation and small-scale players and what are its protective action. Finally, it will introduce the 2 main research questions of this work, specifically, on the role of regulatory sandboxes in fostering innovation and on the ability of the proposal to protect both SMEs and startups in face of increasing regulatory pressures.

The following chapter will introduce the methodology of this work by showing how interviews were conducted, the process of selection of respondents and what have been the main decisions to fit the purpose of this research. Finally, the last chapter will report the main findings of the interview process and discuss these in face of the 2 research questions of this work.

In the conclusion, there would be a summary of the main findings of the work, while also confirming the need for further study on this subject.

1 AI and its impact on businesses

Introduction

Before analyzing the AI Act regulation proposal, this chapter wants to look firstly at what does the term AI mean. By doing so, it wants to point out how there is not a general agreed definition of the term. Instead, AI can be classified as a series of tools and technologies that are based on machines using judgement and cognitive skills similar to humans. Furthermore, it is important to remark the necessity to have some determined conditions for the proper implementation of AI, which have helped already the spread of this technological class across society. In addition, the section concludes with the description of different AI application, their characteristics and how they can be applied.

The second part of the chapter starts to analyze how a cutting-edge technology, such as AI, can impact an enterprise's organizational structure and way to organize business. Indeed, its main focus is on underlining the need for improving infrastructure inside business organizations, in particular those of data management and connectivity. Furthermore, it wants to examine the impact that AI can have on workers' jobs and how companies need to start looking for workers with skills that can mesh well with the technology. Finally, it points out how AI-driven businesses have become more data-centric in decision-making processes, as well as giving more centrality to customers for all the phases of production. All of these aspect lead to firms that are facing less costs and higher productivity.

The following section wants to go even more in depth in AI-driven businesses by analyzing how these organizations work in their daily routines. It first looks at how they have transformed their processes and operations and the advantages that can provide to businesses. Subsequently, it wants to explore briefly some key sectors that have seen staggering benefits from the implementation of AI.

The chapter concludes with an analysis of possible risks factors of AI implementation for enterprises. Furthermore, it wants to point out how these can have a negative overall impact to business operation and the necessity to develop a strong regulatory framework to be able to create a proper functioning environment for an AI-driven business ecosystem that is trustworthy and sustainable.

1.1 What is AI?

Throughout the last century, there has been an immense fascination towards the idea of machines being able to think, act and interact like humans. Many academics believed that this

would be a huge development for society, leading to greater gains in terms of wealth and well-being of citizens. At the dawn of AI's study and research, the overall belief was that computers in the long-run will supplant human labor completely.

However, this has not proved to be the case. Instead, this technology has most of the times been created to help the work of humans, not substitute it.

Today, the concept of AI, coined in the last century by academics such as John McCarthy, has become reality thanks to different waves of technological advancements. This constant progress has made computer able to perform different type of tasks in various areas in almost complete autonomy from human interference.

However, the notion of AI has evolved even more and in unforeseeable ways. Indeed, the definition of AI as the capacity of machine to think and solve problems in a similar manner as humans, is somewhat limited to what AI can do in the modern times.

Indeed, AI is regarded as a general-purpose technology, which means that it can influence an entire economy and society as a whole in a profound and transformative way. In this sense, the different applications of AI can have various effect on citizens and directly on firms. As it will underlined later, it can affect different areas of businesses from marketing to operation optimization, as well as various sectors from healthcare to finance and manufacturing.

In turn, this characteristic of AI has created a difficult situation for finding a common recognized definition. It is possible to find an infinity of possible meanings on such researched concept, in particular its different applications make it even more difficult.

In general terms, AI can be defined as "machines performing human-like cognitive functions (e.g. learning, understanding, reasoning and interacting)" (Baruffaldi et al., 2020). In particular, AI can be summed up with its abilities "to interpret external data correctly, to learn from such data, and to use those learning to achieve specific goals and tasks through flexible adaptation" (Haenlein and Kaplan, 2019).

However, this unclear categorization of the concept of AI can be problematic for different reasons. Firstly, it could easily mislead the general public on identifying AI applications, since they can be of different nature and vary across different sectors. Secondly, as it will be seen later, the problem of not having a clear definition could also put in a difficult position the legislators that want to regulate these technologies. In this sense, the definition chosen by these actors could easily create regulatory asymmetries by excluding some AI application or, on the contrary, it could incorporate components that are not completely considered as AI application within the scientific community. In turn, these various difficulties could easily lead to the place of regulatory constraints that are not equivalent across different actors of the AI ecosystem.

Finally, this unclear definition has made also difficult the creation of AI strategies by national governments. Specifically, the variety of these technological class makes it difficult to understand by non-technical professionals the differences between various applications, thus, leading to difficulties in identifying all these components and leading to possible exclusion of some categories within investments plan for their development. These scenarios can be especially common when there is a lack of technical competences on the topic that can help to clearly identify the various components of the term of AI.

To sum up, AI cannot, thus, be classified not as one product, but as a series of technological application that have the ability to recognize, learn and act, with the capacity to adapt through time and learn from experience (Akerkar, 2019).

1.1.1 Necessary conditions for spread of AI

As it will be also underlined more in depth in later sections, there are various developments that have helped the spread of AI within business environments and make its implementation easier. In this paper, there are considered 4 in particular as crucial factors: greater data availability, improved connectivity infrastructure, increased computational capacity of machines and better human competences relating to AI.

In regards to the first point, there has been a great consideration on the importance that data has for businesses in providing a new potential for growth. In particular, it has been regarded as fundamental the role that data can have in finding other meanings to already existing knowledge.

Similarly, AI to be fully functional needs knowledge, which is provided by data. To be able to gain these valuable insights, this knowledge must be built directly into the systems (Oosthuizen et. al, 2020). For this reason, data has become a hot commodity inside businesses organization that want to use AI systems within their processes and its demand has skyrocketed. At the same time, the availability of data has increased a lot in the last years, which has helped businesses creating, for example, a more informed system of decision-making or demand management.

Therefore, many businesses have understood that data has become a fundamental aspect of their working routines. For this reason, they have started to improve their internal data sources and use it more for improving production or customer relations. For example, data that before was difficult to obtain such as customer preferences or behavior have become a huge pool of information for businesses and an enormous competitive advantage.

At the same time, governments also have started to invest a lot in providing more data sets for companies, especially SMEs, which many times have difficulties in gathering huge amount of

data compared to giant companies, to improve the general economy's performance in face of more data-centric foreign corporations. Furthermore, huge amount of available data is necessary for the development and deployment of AI.

Data is fundamentally important for training those systems that utilize it to provide more insights or problem-solving abilities to obtain further gains through the use of this technology. AI systems, especially those specifically of Machine Learning, need a great quantity of data to work in a proper and functional way. Indeed, many of these systems are trained through huge databases and data to be able to provide better outputs that are more comprehensive of society at large.

Indeed, the more they are trained with quality and comprehensive data, the better they will perform, giving more accurate and reliable predictions, as well as decreasing the possibilities of biased outcomes. This makes AI more "intelligent" with more optimized and efficient results, making these datasets a huge competitive advantage for companies. Thus, making data more available and more complete, creates the perfect condition for further developments of AI applications in all sectors.

In this sense, it has become increasingly important the concept of Big Data. This concept refers to larger volumes of data, with an enormous variety of data sources, having a better veracity of data that truly represent reality (Gregory et. al, 2021). In this way, it can make AI more informed and with a better representation of society and the population under study. Therefore, Big Data businesses can encounter even more competitive advantage through the creation of a deeper pool of information.

However, it must be also underlined that data in itself does not guarantee a complete and neutral representation of reality. Indeed, the way in which data is formed through a process of categorization of reality, especially of intangible events into more specific and quantifiable object, affects the final output of the representation of real events (Alaimo and Kallinikos, 2021).

Indeed, all the process of mediation between data and reality affects the way in which data is able to represent reality and a different manner of extraction may lead to a different interpretation of an event. On the whole, data is never able to represent reality in a complete manner since during the extraction process the information becomes more mediated and transformed by the way in which this event is recorded (Alaimo and Kallinikos, 2022). Thus, it may be too preposterous to state that data is able to represent reality and that more data is able to make machines more able to represent reality.

Although data is regarded as the raw material for AI, it also important for the development of this technology the improvement of connectivity infrastructure. This make the gathering of data, as well as the ability of machines to take decisions and solve problems quicker. It is also crucial for the development of a complete AI ecosystem, since it will make machines more capable to interact with each other and exchanging huge amount of data more quickly across AI physical tools (IoT) and software systems.

Furthermore, a better connectivity helps businesses (but also society in general) to better store data in the cloud and being able to access it in quick times, making processes faster and more independent from other sources. This is directly the key of what is called "Embedded AI", which is an AI application working directly within a device that capture data and information in regards to a particular usage.

Another important development for the spread of AI technologies has been the increased capability of machines in computational power. Indeed, machines have improved their capabilities in calculation and the velocity of data elaboration enormously from just 20 years ago, thanks to the huge advancements made by the ICT sectors.

In turn, these new features of machines make them capable to better gather, analyze and make inferences on data, as well as to be more independent from human interference in performing these tasks. Connected to this point, it is clearly important to have system with a great computational capacity of complicated and great datasets.

A final condition that has proved necessary for the implementation of AI is the improvement of human capabilities in regards to AI. Indeed, it is fundamental that human and machine can be able to complement each other's work in symphony without any friction. For this reason, personnel training has become essential for a better collaboration with AI's application and to capture fully the benefits for productivity.

In this sense, there has been a shift in the academic view over the years, on the role that AI can have on human work. At the offset of AI studies, many believed that in the long-run it would supplant the human workforce, in favor of automated machines capable to do the same job in a more consistent and flawless manner. However, it has been proved by many current examples that this is not actually the case. As will be underline more in depth in the next section, the key to increase the potential benefit of AI for businesses is the capacity to make the collaboration between humans and machine smoother and in continuous harmony to avoid in this way any slowing down of business as usual for any incomprehension among the 2 parts. Furthermore, the proper functioning of AI depends also on the ability of human factor. Indeed, they need to be fully capable in developing, using and implementing AI programs. Thus, it is important that

there is a complementary development of capabilities of human subjects with machines, making this working ecosystem fully capable of functioning efficiently.

1.1.2 AI main applications

Following this brief presentation of the main developments that fostered the spread of AI, it will be described briefly what are the main AI applications and tools that affect businesses. In this section, it will be underlined the presence of different kinds of application of AI that can impact working environments, describing how they perform and what potential can bring to the market.

The most notable application of AI is Machine Learning, which is the principal instrument to construct an AI ecosystem. This consists in the capacity of machines to be able to learn through a set of data and, in turn, being able to autonomously make inferences and reason around a determined amount of data to gain valuable insight.

Machine Learning has as its main peculiarity the ability to be able to automatically make sense of data without being explicitly programmed, using the possibility of learning through examples and experiences provided by the used dataset to train the AI system. An example of application of Machine Learning in the business environment is, for instance, in delivering targeted real-time Advertisement campaigns to target specific group of customers, based on a computation of massive amount of data on their behavior (Akter et. al, 2020).

Before being put into work, Machine Learning systems are trained to have a complete knowledge and produce an accurate prediction. In particular, there are 3 types of training of Machine Learning algorithms. The first is called supervised learning, which consists in training an AI system, with labeled data. Thus, it expects the machine to arrive to a predetermined solution to a particular problem, based on a set of already existing examples in the dataset.

Another methodology is unsupervised learning. This type of training is based on unlabeled data given to AI, which in turn analyzes it to find "undefined structures within the input space based on differing parameters" (Caner and Bhatti, 2020).

Finally, a radically different kind of training is reinforcement learning. In this case, the AI system is trained with a goal-focused framework, in which the system chooses the decisions that have higher probability of success, disregarding the ones that could cause failure in solving a determined problem.

Thus, Machine Learning is centered around the concept of extracting valuable insights, in dynamically changing environments, "with a strong emphasis on adjustments, retraining, and updating of algorithms based on previous experiences" (Akerkar, 2019).

In contrast, Deep Learning goes a step further by being able to process even bigger amount of data in raw form, thanks to improvement to the neural infrastructure of these machines, and provider even better and more accurate results from it.

Indeed, it improves even more the results of unsupervised learning, thanks to more accurate and efficient predictions with a minor effort compared to Machine Learning techniques, due to the new access to Big Data and an improved computing power (Akerkar, 2019).

Thus, Deep Learning goes a step further compared to Machine Learning, making possible the process of rawer data in a more efficient and effortless manner, using a multilayered reasoning similar to human's ones. In this way, it improves the AI system work, making it able to provide a better service with more accurate results.

Despite being the main applications of AI, there are other different technologies, which make the implementation of an AI ecosystem and its performance more effective and efficient. A great example are Natural Language Processing and Speech Recognition. These functionalities enable the collection of various kind of data referred to natural language or speaking, which in turn can be used to better improve a service or a product, thanks to the constant and immediate feedback that can provide to the overall system. Apple's SIRI is one of the most famous programs of speech recognition, which is able to understand human language and provide the services requires, collecting data on the requests and the level of satisfaction of the costumer.

Another technology that is able to complement and amplify exponentially the potential of AI is the so-called Internet of Things. The concept of Internet of Things is centered around the concept of having physical objects connected between each other and to a central system. Indeed, these could be sensors attached to products, or even manufacturing machines, collecting data on the users, usage and the wear-and-tear of a product or machine. This data is then transmitted to a cloud services and utilized to improve the performance of the whole AI ecosystem. However, it is important to note that to be able to fully capitalized these data is needed an advanced AI system to handle it efficiently.

Finally, cloud computing is also a fundamental aspect of the AI ecosystem, since it permits a remote access to both software and hardware resources. In this way, it makes easier the collection and retrieval of data across the various step of the ecosystem, providing to businesses a simple way to move data in an easier and business-friendly way across every actor of the ecosystem.

1.2 AI's impact on business organizations

In the last section, it was underlined what can be defined as AI, and what conditions are necessary for its implementation. The following portion wants to highlight how AI can impact business organizations as a whole with the goal of increasing productivity and reducing costs, looking at the possible changes to the way of working and the internal organization.

As stated before, AI is a general-purpose-technology, meaning that it can have an impact to various sector of the economy, not being limited to one small area of it. Similarly, AI can affect businesses in all its steps of the value-chain. Indeed, it can create value in different places of its processes, by changing completely its inner working.

To show this potential, it will be underlined first what a business needs to do to be fully capable to benefit from the potential of AI. As with the implementation of other technologies into a business, it is necessary to create the right conditions to achieve the potential of this innovation, without the disruption of businesses' working capacity and workers' ability to perform their task in the best possible way.

At the same time, AI's applications can revolutionize the way in which companies are organized and how they organize their production process, creating a new value creation mechanism for AI-driven businesses.

For these reasons, it is fundamental to implement both organizational, operational, as well as cultural changes to a business to really grasp the benefits of implementing a new technology with a deep lasting impact, such AI in the case under study.

1.2.1 Steps necessary for AI implementation

Considering what in the previous section were defined as the necessary developments to spread the use of an AI ecosystem in various sectors, this section similarly wants to highlight briefly first what any enterprise must do to implement an AI ecosystem into its inner workings.

As highlighted previously, data has been defined and regarded as the fuel to the proper functioning and performance of AI systems. For this reason, it is fundamental for businesses that want to implement AI solutions to focus their efforts in creating a business environment centered around data. "For successful AI transformation, business need to adopt a better data ecosystem with data governance, use cases with business value, analytics techniques and tools, workflow integration and an ambidextrous organizational culture" (Akter et.al, 2020).

To be able to achieve such changes, there are different steps necessary to be implemented by firms. A fundamental aspect is the improvement of the data management infrastructure, meaning that businesses should improve substantially their data warehouse systems. In this

way, it will be possible to collect all the data information coming in an easy and smart way, which makes its usage quickly available for machines.

It also fundamental for enterprises to keep these data warehouses constantly updated. A database that goes out of date cannot paint a proper picture on potential consumers for the AI system and the business itself, since costumers can change their behavior in the meantime (Corrado et. al, 2021). In turn, it will lead directly to the creation of products or services that are outdated and do not serve properly the general public, being only a further expense for companies, without adding much business value.

In a similar fashion, businesses have started to grasp the potential that data of the current business environment can provide to the overall work of the company. For instance, data on usage of machine can help determine the potential need of maintenance, in order to prevent unexpected breakage and, thus, work stoppage. Similarly, data on sales figures can feed Machine Learning algorithms with the necessary tools to perform a prediction of demand for a particular product, as well as showing what could be the best periods for selling such item or its most consistent group of buyers.

At the same time, many SMEs have started to use external databases to train their AI system to have as much as possible information about business opportunities and their potential customer base.

This point has been understood a long time ago by big corporations, especially digital ones. For example, Amazon has spent many resources in creating a data ecosystem in its company, by putting data as the center of potential gain and business opportunities. Indeed, it uses data to find the best possible suggestions for consumers, through their behavior on the platform and aggregating this to generate macro-group of costumers with similar tastes.

Although the creation of proper data management infrastructure is a fundamental aspect of implementing a new technology, it is similarly crucial the impact that this technology can have on the human capital of a particular company. Since they will be those that use and collaborate daily with these systems, they are required to possess the necessary skills to be able to work in harmony with these technologies.

In this sense, it is also critical to have workers that, in the case of AI, possess a so-called AI literacy. This term means that they have the proper skills to function in harmony with said-technology, being able in this way to untap the potential that it can bring to a business processes and operations.

The key to develop an AI literacy into an organization is in the training process. Indeed, it becomes now fundamental to guide the workers on gaining new skills that are more required in

this case. Training should be based for staff members on increasing their capabilities to work effectively with AI, while also understanding their use and applications for each appropriate situation (Akerkar, 2019). Similarly, companies may start to look for future personnel that possess determined characteristics which are considered as better suited to work in collaboration with AI.

The need for a collaboration between machines and human in the working environment is due to different factors. For instance, machines cannot do every task in a company, specifically those that need the use of judgement and in general human intelligence. Thus, as it will be underlined later, machines can help human make decisions, but are not capable to take decisions themselves because they are not yet able to consider other factors, such as human feeling, prioritization or the ability to take a stand in a trade-off situation.

In this sense, AI could facilitate the work of employees by making them focus on mansions they can achieve better than machines, while the more repetitive and mechanical tasks can be delegated directly to machines (Jüngling and Hofer, 2019). These tasks of computation and organization of data are better suited by machines, which are not prone to human errors and are more consistent over time. In this way, business organization will create a business environment in which the work of human and AI machines is constantly complemented between each other.

In a similar vein, the implementation of AI into a business organization also affects the way people's work is rooted and organized in a daily routine. For instance, an important aspect that many times is overlooked in the automation of jobs is improved worker's security.

Indeed, the transformation of jobs in different sectors has led to the improvement of workplace safety, thanks to the automation of riskier processes like the assembly phase in a factory. The reskilled workforce, which is now required to perform tasks that are more specialized, is also in a less risky position compared to the past which may improve overall work safety (Aglietti et.al, 2019).

1.2.2 AI's transformative power in how businesses organize

As stated throughout this work, data has become the central aspect of businesses. Companies have finally understood the potential that data can bring to the production process, being also a fundamental resource of advantage in face of enormous competition. In particular, Big Data can produce and generate usable information, in particular it can affect greatly how business is going to be done (Chaveesuk, Khalid and Chaiyasoonthorn, 2019).

The great emphasis put in the analysis of data by AI applications has led to greater overall efficiency, as well as continuous innovation inside businesses. In turn, this application of AI

permits them to have a clearer picture on how to achieve their business goals, as well as providing them with enormous possibilities to create value through the use of data analytics.

In this sense, data can be used for different tasks and objectives. For example, it has become the primary engine for decision making in many organizations (Yablonsky, 2019). As underlined before, this data can come from internal and external sources, such as external available databases or the analysis of internal transactions. The latter are particularly important because they can provide a further information on how the company is going and whether there is a potential gain that are not yet exploited enough. For this reason, many companies have started to create data warehouses and management system, which are able to better manage the huge commodity that data has become to do business. It has become such a potential source of value that it has also generated a competitive battle among companies to gather as much data as possible. Furthermore, data can also be obtained in our physical surroundings, through the uses of AI personal assistants (like Alexa by Amazon) and even IoT, which are capable to transform every single moment of human existence into valuable data. (Akerkar, 2019)

However, it is crucial that these databases are rich enough to be able for AI application to produce a complete as possible picture that can influence possible decisions, like potential demand, competitor strategies, or cheaper production processes. These sources for decision-making permit to companies to make decision through insights that were less visible and more difficult to obtain in the past, but now AI's data analysis has made it more available throughout the economy. Furthermore, the use of Data-driven AI decision-making adds value to data, in particular Big Data, and it is a crucial aspect for the successful use of AI to innovate enterprises (Yablonsky, 2019).

Finally, the use of data is also fundamental for creating a closure to the final users. Indeed, the usage of good quantity and quality databases for training AI machines, especially Machine Learning, will create a strong relationship between the companies using these technologies and the final users, generating a perceived user value (Gregory et.al, 2021).

This last point connects well to a great change that digitalization has brought to model of business and that AI has amplified even more, that is, the centrality of customer in all phases of the production process to have as much personalization as possible. In the past, production was solely based on creating products which would incorporate the biggest chunk of customers through a one-size-fits-all approach. On the contrary, today business focus a lot on creating products which are greatly personalized to different category of costumers. This is possible through the usage of many data sources on customers and through the aggregation of many of

them, it is possible to make tastes-based recommendations, making the business model more customer centralized.

In this sense, AI led businesses put in the same way the single customer at the center of their production process. For instance, many businesses, that use Machine Learning, utilize it to analyze customers' purchase history, to make personalized product recommendations based on their past tastes.

Furthermore, AI solutions have also improved customer services, by creating more personalized services and experiences for customer, which help even more businesses in creating a direct connection between them and their final users. Indeed, AI innovation has led directly to better customer engagement and accelerated rates of innovation (Jyoti et.al, 2019).

The creation of greatly personalized experiences can have a deep lasting impact on businesses performance. For instance, Gerbert et.al (2018) state that the creation of "personalized experiences can increase revenues by 6% to 10%". Thus, it can become a great competitive advantage for those firms that are able to leverage the potential of this technology.

Successful digital companies, like Amazon, have understood these benefits and have been able to become a giant in the economy, being able to conquer huge shares of customer market and hampering any attempt of potential competition by buying these potential threats immediately. Amazon is also a good example on how companies can use personal data of consumers, that are gathered through transaction histories or researches on the platform, to continuously propose new products that may interest customers. In this way, Amazon's ecosystem is able through the use of personal data of customers to perform deeply accurate predictions on their tastes, generating a huge value for users and improving the company's revenues. Thus, AI applications are nothing more than a tool for business to accomplish customer engagement and the value lies in the effectiveness of serving customers well (Akerkar, 2019).

All the impacts that AI can have on businesses shown in this paragraph tend to increase the general productivity of these companies and it can be done in many different ways. For instance, it can help decrease the cost of labor, as well as creating a situation of complementarity between humans and machines working together (Agrawal, Gans and Goldfarb, 2019). In general, the advantage of AI is its ability to be scalable, durable and capable of continuous improvement, which will in turn generate different flows of productivity.

Furthermore, "AI centers on its potential to increase productivity, by reducing costs, complementing labor and spurring complementary innovations" (Saint-Martin and Lane, 2021). However, it is not an automatic conclusion that AI implementation will lead to better productivity. This can be due to different factors, especially the inability to attract skilled

workers or the setting of proper functioning infrastructure. Thus, there can be a risk of amplifying the divide between smaller and bigger companies due to the difficulties to implement AI in a proper functioning way immediately.

However, at the same time, smaller firms have been capable to readjust and implement AI-based technologies in "their production processes at a scale allowing the creation of a significant impact on productivity" (Damioli, Van Roy and Vertesy, 2021).

In conclusion, AI-powered solutions are able to create value and transform businesses in many ways. For example, AI-driven businesses are able to create huge value thanks to its ability to enable overall innovations in the company. Indeed, these technologies used permit to change how products are made and introduce AI-based new products, new services and new business models (Cao, 2021).

Thus, AI can have an enormous impact on businesses as whole, it can affect their way of doing business as well as the overall culture inside the organization, making it more data and customer personalization centric. The next section will show even more this by looking at how AI can improve firm's production process in particular, looking also at some particular examples of specific sectors.

1.3 AI's impact on production process in different sectors

The previous section pointed out how AI can transform companies that are switching towards AI-driven processes, looking in particular at how data has become central, the new skills required to workers, as well as the possibility to make products and services more personalized for customer, leading to overall increased productivity.

This next section wants to go more in depth in this analysis, by studying how AI can affect the daily routine of work, how processes are transformed inside a company and the impact that can have in some sectors in particular.

1.3.1 AI's impact on businesses' operations

As pointed out throughout this chapter, AI can have a deep lasting impact on how companies do their business. In this sense, any AI tool may improve the functioning and efficiency of a business' operations being those online or physical. For example, the management of warehouses or the assembly line in a manufacturing firm can be greatly optimized by AI applications, by collecting data on how these processes are performed to find a way to increase

speed and, therefore, productivity. Similarly, this section wants to analyze in particular some macro areas of processes that can be further optimized and make it more efficient by AI.

The process of monitoring business operations is a fundamental aspect of many ventures to keep production constant in an efficient and effective way. At the same time, it can help companies to be able to find any possible fallacy to production processes and to correct them as soon as possible.

AI applications can improve even more the monitoring of systems and processes, doing it in a quicker and responsive way. For example, Machine Learning can help predict systems' future functioning and situation thanks to sets of data on the current work and production.

Furthermore, AI can also permit firms to create a system of predictive maintenance of production machines. In these systems, there is the possibility to predict accurately through the use of data from past production when a failure may occur and be repaired before it can impact directly the production process. Obviously, this new opportunity presents enormous benefits for firms and their employees, by reducing maintenance costs as well as the resources spent on it.

In addition, "predictive maintenance can also result in a reduction in maintenance operations and costs, since maintenance is only conducted when it is predicted instead of being conducted at fixed intervals" (Eager et.al, 2020). Finally, AI-enabled monitoring can also be instrumental to quality control, as this technology could be capable to examine products components on the assembly line and avoiding possible defects for the final product.

The control of the proper functioning of business operations is a fundamental aspect of AI and they are even more useful in guaranteeing the proper functioning of automation, ensuring the realization of its benefits. The primary goals of the usage of AI tools in these processes is the ability to respond immediately and swiftly to any event that may affect the industrial process, while still targeting an increase in productivity, with a decrease of labor and general costs.

Some example of these application to businesses activity can be the use of autonomous robots in warehouses for the movement of goods. Amazon is one of the most famous companies to use these inventory management systems inside their warehouses. For those applications, machines know through sensors where they need to store some products, regardless of whether they have a usual position or not. Indeed, the Deep Learning functions permits to those robots to identify and store correctly an object even not in predefined position, making makeover precise and improving robustness of processes (Dash et.al, 2019).

In this way, there is a belief that AI will perform these management tasks more effectively than humans, decreasing at the same time the risk of injury for the employees, thus, creating a safer workplace.

Another application of control system of AI is the management of the factory's energy resources. Specifically, it can analyze what are the conditions of the weather outside and regulate consequently the level of heating or of air conditioning, leading to a decrease of energy consumption and its monthly costs.

As underlined before, AI can have an enormous impact in also optimizing the production processes, making it more data-centric and thus more accurate to what are its business criteria to fulfill. Furthermore, these types of technology tools have the ability to analyze production's environment as a whole, instead of focusing one element at the time, thus, enabling a complete optimization of the work (Gerbert et.al, 2018).

An area in which AI can have a great impact in optimizing its functioning is product design. Indeed, designers can be facilitated by putting just some general inputs, then the AI system is able to generate alternative designs through the use of machine learning algorithms. In this way, the AI applications can establish whether a product is manufacturable, saving time and money for the testing process. At the same time, it can suggest alternative for design for these products based on the deficiency data of the product. In this sense, AI can help create autonomous self-learning products (Grover, Kar and Dwivedi, 2020).

Similarly, the production process in manufacturing facilities can be made more efficient through the use of AI applications fed constantly with Big Data, making possible in this way a continuous production process without any stoppage even in case of use of the wrong component by replacing it instantly with a created digital copy (Akerkar, 2019). Furthermore, those processes can be also optimized through the collection of data in all phases of production to gather as much information as possible to understand how to improve and innovative those functions for a company. Thus, AI has the ability to build connections among these gathered data that may lead to future innovations to the current way of working inside a firm (Caner and Bhatti, 2020).

In terms of innovative power, it is important to underline the role that AI's predictions can have for businesses to improve inner working. Indeed, better and more accurate predictions can be a huge game changer for firms in various areas, such as demand management or price setting of products.

For example, AI applications are able through the processing and the analysis of enormous data that can include costumers' preferences, product quality compared to past models, sales data or

even external factors, such as how the market is performing, what are the main competitors and what is a price in the market for a similar product; it is capable to study all this information and provide a reliable and accurate picture of demand (Dash, et.al, 2019). This process is called demand forecasting and it is a huge advantage for companies to have a very accurate prediction of what the demand will be.

Firstly, it will help them in allocating the proper resources (capital and human) for a specific product and in case relocate those for projects or tasks that require more help. In turn, this process helps enterprises to reduce costs and spend resources more efficiently and thus increasing overall productivity.

Furthermore, a similar functionality performed by AI also saves time and effort of humans, which would work on this otherwise, whilst at the same time providing a more accurate result for the company.

Predictions made by AI systems can also be crucial in analyzing whether a particular product would succeed or fail in the market, providing also the reason for this expected result.

Finally, many enterprises have employed price-setting algorithms, which are able to adjust prices autonomously also in base of the product strategy that is predefined at the start. This use of AI tools permits firms to have more customer-advantageous prices compared to competitors and based on various data sources. In this way, companies can know precisely what customers are willing to pay for a particular product. In addition, they could also forecast how consumers may respond to a future price change of the same product (Chalmers et.al, 2021), making a crucial further insight that can impact deeply the production process.

Connecting to this last point, customer relations have become an area of enormous usage of AI applications. These technologies provide enormous insights in this area, which, in turn, help enterprises in having a more direct relationship with customers as well as be able to produce products and services that are more personalized towards customers' needs. In this sense, businesses are able with the use of AI to transform data about customers as useful and specific type of market knowledge (Leone et.al, 2020)

This newfound ability of companies can be obtained obviously from the enormous data available from customers, such as from e-commerce platforms, which make this data easily available through its many interfaces that direct customer behavior. The collection of interactions of users with the platforms provided insightful data on their behavior, specifically on their tastes, time of the day they are more inclined to look for products and the specific characteristics they are looking for. Furthermore, it provides other useful information such as demographics or interests that permits to spot what are the best suited audiences for their brand.

In this way, it allows enterprises to trace the buyer journey using Deep Learning algorithms and can predict what customers are likely to buy even before they have decided (Akerkar, 2019). In turn, this will likely increase customer engagement and experience since their tastes are fulfilled immediately, as well as improve customer loyalty and the image of the company.

In addition, the analysis of customer's data helps immensely AI-driven companies in being able to discover new customer segments that may appreciate their products (Caner and Bhatti, 2020).

1.3.2 AI's impact in various sectors

After looking at how AI tools can have an impact on production and increase overall value to enterprises, now there will be a deeper focus on some sectors, looking at how they are impacted by this technology and what tasks they can help to perform.

Before analyzing in detail these sectors, it is important to underline that AI can have a bigger impact in some sectors rather than others. For example, those that tend to have a deeper and more close relation with the general public would be more impacted by the use of AI tools in comparison to sectors that are more socially excluded. The principal economic sectors in terms of AI implementation into their business models are financial services, automotive, high tech and telecommunications, with around 30% of firms having adopted one or more AI technologies, while less digitized sectors include travel and tourism, which stands at around 12% (Eager et.al, 2020).

Manufacturing has been transformed radically by this transformative force that is AI. Here, AI technologies work alongside humans to perform several operations as a collaborative duo, making work more efficient and effective for both.

In addition, as it was underline before, AI's predictive power allows manufacturing companies to take smarter and more cost-effective decision regarding their production process. At the same time, it has facilitated these enterprises to integrate production and customer's data at a real time basis to be able to produce a good that is best suited for client's needs and tastes and, in turn, also cut overall costs and reduce waste.

Another fundamental aspect of AI is that it has increased considerably workplace safety through both the use of automation as well as the reduction of manual and riskier tasks for human employees. Finally, AI enable manufacturing has also helped the development of "collaborative agility, which is the ability to adapt instantly to changes in demand and the evolution of regulation, input prices, technologies, and other parts of industry landscape" (Dash et.al, 2019).

Retail is also another sector that has been greatly influenced by the implementation of AI into its main processes. This technology can become a great competitive advantage for those

companies that use it compared to more traditional retailers, making them more digitalized and customer-centered. In turn, AI-driven retailers have been able to increase the number of customers through an improved and more personalized customer experience, creating a sense of loyalty from customers.

To grasp at the highest level the benefits of AI, retailers should focus on implementing this technology throughout their value chain and change their organizational structure to embrace fully AI and all its applications (Cao, 2021). In this way, it helps them make all of their processes more efficient and optimized creating in turn more value for both their business and their customers. For example, it can be applied to areas of customer management, as well as those of supply chain and store management, thus bringing benefits for all these phases of the value chain.

As underlined throughout this chapter, the customer analytics, that is, the study of customers' data, is a fundamental aspect of all AI applications for business. However, a sector that can gain a particular advantage from this characteristic of AI is marketing.

Indeed, enterprises in this field are able through the use of AI applications to study the baseline customer group, analyzing how much are they prone to make a purchase relative to a particular product or service. In this way, they are able to create highly targeted advertising campaigns taking advantage of suggestions produced by the AI application that have analyzed all the customers' data.

In addition, AI can have an enormous impact for network industries (telecommunications, energy or electronic communications) in the management of production and distribution. Indeed, this type of technologies can help companies in these sectors to make production more rationalized in face of shifting market conditions and overall demand.

A similar use of technology has enormous benefits for both companies and society. On the one hand, it helps companies save a lot of costs, by both regulating production based on projection of demand in the near future, as well as creating a more efficient distribution chain based on need. On the other hand, the creation of a more optimized and efficient production system can have enormous environmental benefits. For example, it can regulate the use of energy inside a house based on motion sensors, that can detect whether they are empty, thus creating a heating schedule and optimizing energy use (Bughin et.al, 2017)

A sector in which unfortunately AI has had limited usage, but could provide enormous benefits is Healthcare. The predictive power of this class of technologies could improve immensely the care system as a whole. For example, AI applications applied to healthcare can determine the risk propensity of a determined subject to certain diseases based on analyzed data regarding its

lifestyle, its past medical conditions or its demographic group. This mechanism of disease propensity prediction can be an enormous instrument for doctors to be able to decrease people needs for care, focusing more on prevention.

In turn, these applications can have a great impact in decreasing the pressure that hospitals endure, especially for lifestyle related diseases, that can have a higher rate of prevention compared to viral ones. Thus, AI must be considered a crucial step for healthcare system for "providing better and safer care and to contribute to a more effective use of resources" (Flora, 2013).

To conclude, it is important to underline also the impact that AI can have for banking and finance in general. The improved computational power of newer AI systems has helped many banks and credit institutions to calculate more accurately the risk level of possible opportunities, like conceding a loan or a mortgage. Indeed, these systems are able to analyze all customer data in a more complete and impartial way compared to human judgement, providing fairer terms for both credit institutions and clients. At the same time, it has become a crucial mechanism to better detect fraud or fraudulent behavior from clients, especially in the cases of money laundering, through its speed in analyzing enormous quantities of data.

1.4 AI's risks for businesses

To conclude this chapter, it is important to spot what has led to the development of the here-studied "AI Act" regulation proposal of the European Commission. Specifically, the risks and problematics that AI can bring to different businesses and what are the best strategies to mitigate them. This section is also important to underline what are the problems of this cutting-edge technology.

In turn, it will help directly understand what could be some possible mitigation action, making AI a more secure and trustworthy technology, with an improved relation with the general public, leading to widespread adoption by businesses and increasing productivity and revenues throughout the national and European industry.

Before looking at these sources of risk, it is important to underline that in Europe the adoption of this technology in business organizations is still considerably limited compared to other economies, like China and the US (which the EU regard as its principal competitor globally). For example, according to a study performed by the Center for Data Innovation (Castro, 2019), the EU lags considerably to these 2 other economies in both AI adoption by firms (18%) to

respectively the US (22%) and China (32%), while it also trails to the US in terms of number of AI start-ups per 1 million workers (8.4 to 2.9).

To understand why there is this big discrepancy between Europe and these other economic areas, it is important to look at some sources of risk and obstacle to the proper implementation of AI across companies.

A first problem for businesses that want to implement AI is of organizational nature. Specifically, many enterprises lack a predetermined and clear strategy on how they want to implement such technology and what area of their business in particular they want to transform. This can create enormous problems for companies, since this condition can create a lot of disorganization and confusion putting a huge obstacle to change and transformation.

It can hamper this process by also, for example, leading to the creation of a cultural resistance among employees, which do not see at first the benefits of implementing such technology due to the fear of losing their jobs eventually. At the same time, they can have a sense of distrust with machines, decreasing the collaboration with these 2 parts, which, as pointed out before, is crucial for the proper functioning of AI across business.

A proper well-defined AI strategy by companies can decrease this sense of distrust by preparing workers on how their job can be improved and made easier by the use of AI. However, management boards want to transform and improve their business by implementing new technologies, but in some cases, they do not know already in advance how they want to achieve such transformation, disregarding the problems that can cause with people and in organizing business.

In addition, an increased knowledge on the benefits that AI technologies can bring may well facilitate this takeover process and diminish the contrasts for this technology.

A further problem for enterprises that want to implement AI in their value-chains is the cost that these technologies could represent. Although costs of implementation have decreased over the years, they still remain a huge problem for many businesses, especially Small and Medium Enterprises (SMEs), that lack the same level of possible investment compared to larger organizations.

Indeed, many times they may lack the funding necessary to be able to adopt this kind of technology, compared to bigger or more internationalized firms. This could be a problem in creating a wider gap between these SMEs and larger enterprises, since the latter would have a greater competitive advantage after they have started using AI applications to improve their business. Thus, it can hamper "the opportunity for European SMEs to start adopting AI and

incorporating them in their processes, which usually tended to rely on large R&D and access to talent which was out of the reach of many SMEs" (Eager et.al, 2020).

Furthermore, many SMEs do not begin this process of transformation even if they have the economic capabilities in fear that the short-term costs of going through this process will significantly outweigh the long-term benefits of a more optimized and effective production process, since it is necessary to invest in other additional instruments such as improvement of data and connectivity infrastructure.

AI could also create problems for business also in its need and use of data. Firstly, as stated above, data is a necessary precondition for the proper functioning of AI systems. However, it is not a simple task to gather massive training databases. This can have an enormous cost for companies or they may be ostracized from the market by large organizations like Amazon.

The inability to collect a proper and complete data set can cause AI application to have inherent biases that can cause huge reputational damage for a company. For example, the development of AI systems with an unwilling bias inserted to it that affects a particular group or part of society can cause a lot of damages to both customers, as well as reputational damage for the company.

This is especially the case when there is no use of representative and informed dataset to train the AI system, which in turn can amplify the impact that these biases already have in society. For example, credit institutions that tends to allow more loans to white people than of other races, even though they have similar credit score, is a form of algorithmic biases.

However, similar situation can be seen in the judicial field (assisted decisions on probation) and health system (decisions on priority of surgery). A risk related to the working field is the risk of improving the automated work compared to the human one, despite non-existing advantage in terms of quality of work, just a cost one.

Finally, the improper management of users' data can have reputational damage by infringing customers' privacy rights. Although this area is regulated specifically by the GDPR of the European Union, it is not clear if this legislation applies completely to AI applications. Thus, the proper mismanagement of users' data can have enormous financial and reputational damage for companies that use enormous quantities of data.

Similarly, AI systems can cause a huge reputational damage for companies that imply those if they are not enough protected by external threats. Cyberattacks can enter and extrapolate all of data from companies' data warehouses, if not protected in a complete way. Thus, it can have enormous damages for companies' reputation if these breaches happen and, in addition, it can

be even more so for smaller companies with a smaller customer base compared to larger organizations.

Finally, a great problem for the implementation of AI is the lack of trained employees with the skills necessary to work in collaboration with its applications. This could be due to a lack of skilled workforce inside the companies, thus needing to face costs of training for all the unprepared workforce. On the other hand, many economies may lack within themselves a proper workforce with the required skills if there is not enough investment in education and R&D. This means that the problem of unskilled workforce could depend more on the economy as a whole than on particular companies, being a national or continental problem.

To solve these problems, both Europe and Member States, such as Italy, have started an overall strategic plan for the spread of AI in the economy and, especially, among SMEs. These programs focus a lot on providing funding for companies, as well as sources of data or improving the research (and, in turn innovation) for this technology. Furthermore, they have invested a lot in improving the educational system for a more digitalized society.

Through the description of AI potential risks for businesses, it looks fundamentally necessary to have a more regulated environment for this technology, even more considering the impact and the wide range of implications it can have on society. "Also, because in the absence of human-driven ethical norms, commercial self-interest and technological evolution that incorporates emotional AI will likely lead to negative unintended consequences for commercial organizations and society at large" (Yablonsky, 2019).

In this sense, it is important to underline that a proper national AI strategy, composed of targeted investments in encouraging businesses to adopt the technology, create programs that train the future and current workforce with skills that may be best collaborate with AI, an improvement in the data facilities in general and more programs that encourage enterprises in investing for a proper and clear AI strategy inside the business environment.

Finally, it is also fundamental for the EU, as it is attempting to do, to improve the regulatory setting around this technology applications making the AI ecosystem more secure and trustworthy for the general public, thus, improving the collaboration and the environment for all the actors of the market.

In turn, this will lead to proper benefits for every part of the ecosystem, making products more targeted for customers, without infringing their data protection rights, as well as improving the gains of AI-driven businesses by increasing the conditions for flourishing even for SMEs. "Because AI-enabled products have automated decision capabilities and AI is a fast-emerging

technology, regulation need and addressing ethical questions are critical parts of the successful implementation AI in business" (Caner and Bhatti, 2020).

Conclusion

In conclusion, this chapter wanted to introduce as best as possible the topics treated in this research on the possible effect of the European Commission's proposed AI Act regulation. In doing so, the primary goal was to describe what is AI, the impact that can have on businesses, as well as some possible risk factors in adopting this technology inside a business environment. As pointed out above, the concept of Artificial Intelligence lacks a commonly accepted definition, but for this study it has been used a more general notion that describes AI as machines with similar skills to human cognitive functions. This broad terminology can incorporate best the various applications that are featured inside the concept of AI.

Despite this simple definition, AI can have a deep lasting effect on businesses. Indeed, it can transform completely their organizational structure, how their structure their work, as well as what is required from their employees. As a demonstration of this huge changes brought by this set of technologies, it has been underlined how both at organizational and operational level data (especially about customers) has become a central feature. It is increasingly to have more accurate data as possible to better organize work, as well as being able to produce more goods and services that can provide a higher level of personalization for customers, creating a great sense of loyalty inside a customers' base.

Furthermore, it has been analyzed briefly as examples, how AI can impact various sectors of the economy and how it has brought a lot of innovation inside various sectors that have started this process of transformation.

Finally, it has been pointed out some possible risk factors for the use of AI inside of businesses environment. In particular, it was underlined how the management of consumers' data and how it is used by companies can be a huge source of risk for companies especially in terms of reputational damage.

Therefore, it points out how it is necessary to set a proper regulatory framework for this technology to be able to create a more secure and trustworthy environment around AI. In turn, this could lead to a higher level of adoption inside the European economy, which is still low compared to China and the US, leading to higher level of productivity and creating a more globally competitive AI market inside Europe. This can also create a higher level of customer's

trust around this technology, which will in turn bring more personalized product that are crafted around customers tastes and behaviors.

2 The AI Act regulation proposal

Introduction

The previous chapter wanted to underline how AI can affect business organizations in different ways. It desired to show the positive effect it can generate for companies, while also underlining the challenges and risks for those that want to implement this technology within their business models. For instance, it showed how this technology class is able to make production more efficient through a decrease in bottlenecks and a higher knowledge of demand, as well as more personalized production thanks to users' data regarding gather regarding their preferences.

However, it also pointed out how AI system, that possess inherent biases, could easily display these on consumers by discriminating them. This could be particularly problematic when it is operated by a company that may affect people's direct wellbeing. At the same time, it was also underlined how AI capacity to affect different areas of society and business needs a lot of strategic planification, that has been missing in Europe and Italy until recently.

Unfortunately, the current environment for European companies that want to grow in the AI market proves to be not helpful in this sense. The principal problems faced by companies, especially small-scale ones, is that AI system are costly for both the developer and the implementor, and most companies may lack the funding necessary to attempt such transformation. In addition, many companies do not see the benefits in the long-run of implementing such technology, when it is faced by a short-term high level of additional costs. This can be due also to the lack of both technical and general competences on the benefits of AI technologies within the current environment.

In turn, these obstacles can discourage the will of companies to digitalize and implement an AI system inside their companies. Thus, it could altogether increase the gap between the European market and foreign ones in terms of innovation and productivity. Thus, there is the need to inverse the course before the gap becomes insurmountable.

On this premise, it was drafted the AI act proposal by the European Commission. This piece of legislation wants to create a more secure and trustworthy AI for the European Union. In particular, it wants to hamper some risks that AI can cause to the general public, creating new requirements that both AI developers and deployers must follow. This regulation covers, not only products that are directly AI systems, but also those products that have their production process influenced by the use of some AI system or have one incorporated in itself. A particular point of emphasis of AI act is in setting up not only the conditions, but also the right system of

governance that can put a direct liability for those that place on the market systems that may pose risks for consumers.

This chapter will concentrate mainly on this legislation to introduce the main research question that will be answered in the final part. These are centered around what could be the regulation effect on the AI innovation process inside the European market, as well as the direct impact on SMEs and startups, which are the actor that are most fragile to change.

The chapter will be divided as follows. In the first section, it will be described briefly the main contents of the proposals. Then, it will focus on risk methodology used in the proposal, looking also at the definition of AI used, analyzing whether this is the most proper way to approach this technology. The third section will concentrate on what are the main provisions for balancing regulatory constraints and innovation, comparing it to the main example of this measure applied to another sector. Finally, it will be outlined what is the proposal approach to SMEs and startups, which are the primary actors of the European market in this sense, looking at whether these measures really can achieve this goal.

2.1 Proposal description

The European Union has made over the years various attempts to improve significantly the conditions inside the single market for both companies and citizens, in order to allow for its proper development under a community approach.

This has been especially done through the drafting of legislative acts (e.g. directives and regulations) that, with a varying degree of binding powers over Member States, have as their main goals to create the proper conditions for the functioning of a competitive market for companies, as well as setting fair conditions for consumers' protection. Thus, these measures have the goal to improve the economy of the European Union and its competitiveness, to really enjoy the benefits of a competitive free market economy.

Although these efforts have been particularly focused on more "traditional" sectors of the economy (e.g. energy, telecommunications and finance), the EU has started in recent years to focus on the digital sector, understanding the deep lasting effect that any deficiency of this market can have on society as a whole. The Commission has started various attempt to regulate this area in recent years, especially after the election of Ursula von der Leyen as president.

For instance, these have been clearly visible in the will of the Commission to curb the power of Big Tech in the European market with the drafting of the Digital Markets Act (DMA) and Digital Service Act (DSA). These regulatory attempts are considered by the EU as a mean to

improve the conditions for other (local) players in the digital market and providing better consumer protections, in the name of fundamental rights and competition safeguard (European Commission, 2020b; 2020c).

Another example is the General Data Protection Regulation (GDPR), which is the European data regulation on the proper management of privacy and personal data and has as its main goal the protection of personal data mismanagement, while creating also a more trustworthy and secure environment for the use of data across the EU (European Commission, 2016).

It is worth noting that the EU is the first economic area that is trying to regulate more strictly the digital sector compared to the more laissez-faire approach of the US or the UK. The main belief is that in this way the EU will become the trendsetter in terms of regulatory approach to the newest technological evolutions.

In this sense, the AI act proposal fits into this context. It is the newest attempt of the European Union to become a trendsetter in digital sector regulation, leading as an example throughout the world in generating the best conditions possible for the proper development of technologies as well as the needed respect for fundamental rights of citizens and fostering a more sustainable and resilient market for Artificial Intelligence. At the same time, it wants to set the proper liability for those companies or governments that do not respect these conditions, and thus cause a harm to society as a whole or groups of it.

In the next pages, it will be looked more in depth the goals and the provisions of the proposal as whole. Then, the following sections will underline some key aspects of the regulation that are most interesting for this research and that will complement the work done in the final chapter on analyzing the impact of this proposal on businesses that apply or develop AI technologies.

2.1.1 General Overview

The AI Act regulation proposal wants to set the common regulatory framework for the AI market in Europe by being divided into 12 titles and a total of 85 Articles, with a further 9 Annexes that help the proper definition of some aspects.

From the beginning, the Commission wants to underline that the creation of rules for AI implementation in the regulation have been thought as human centric "so that people can trust that the technology is used in a way that is safe and compliant with the law, including the respect of fundamental rights" (European Commission, 2021a). Moreover, the overall goal of this proposal is to encourage people, societal actors and businesses to embrace the benefits of AI and to become key players in its market in this field by developing and deploying new solution.

Thus, it also aims to set the proper condition for the further development of the European market in the field of digital technologies, in particular Artificial Intelligence.

As pointed out in the previous chapter, AI systems are most of the times not a product or a good used on their own, but they are specific component or system that can be integrated in a business model or a particular product. For this reason, it is regarded as fundamental the coordination of this proposal with the governance and the conditions set for those items that have now employing also an AI system in their working and are already regulated by the EU. A good example could be the coordination of the AI act proposal with the various pieces of legislation that regulate the agricultural market, making in this way the process smooth for producers that employ an AI system for their business.

Finally, the most important overarching objective of the proposal is to further boost the development of a single market for a safe and trustworthy AI, through a unified approach throughout the Union. In this way, it will prevent fragmentation of regulation across Member States, which will be an enormous problem for both developers and consumers as a whole. Indeed, the development of different national standards for the regulation of AI applications could create an enormous impact to the single market, since the creation of different conditions could generate disadvantages across the Union. For example, it can set more favorable conditions for business, leading to a more uncomfortable position for consumers that will find themselves in a more predatory market.

Furthermore, it will also make the conditions for businesses more challenging, since it may impede or slow down the export of products across the European market, effectively undermining the benefits of a single market. Indeed, different conditions on AI usage will create a huge regulatory obstacle for those businesses that want to export their products throughout the single market, since they must oblige to more stringent or loose standard depending to the country they want to enter. At the same time, it can rise enormously costs because respecting different standards may rise dramatically production costs throughout the supply chain.

In the end, it will impact directly European consumers, which could not have a specific product that is present elsewhere because of more stringent conditions set by their own country.

To avoid in particular this problem, this proposal sets the governance of this EU regulatory aspect mainly in the hands of the Union, by setting a European Artificial Intelligence Board that will propose standards to follow and keeping in constant update the regulation in face of continuous evolution of this technology. However, the enforcement in the national territories will be undertaken by Member States authorities, specifically a newly created National Regulatory Agency. As it will be underlined in the later sections, this can be particularly

problematic, since most of the regulation success lies directly in the hands of Member States willingness and capabilities to match up the standards and the expectations at European level.

To avoid this kind of problems, the proposal desires to place not huge stringent conditions, by focusing on minimum necessary requirements. The rationale behind this decision is twofold. On the one hand, it believes that in this way Member States will be more able to comply with this and guarantee that high levels of compliance are reached across the Union.

On the other hand, it desires to benefit the European market by creating less stringent conditions on companies, which could still almost be freely allowed to experiment and advance the technological innovation process. Thus, they can keep improving the products and goods that enter the market and at the end in consumers' hands.

Furthermore, the concept of less stringent conditions helps also in the ability of setting a minimum common denominator on the conditions that may pose risks and problems to AI, which in turn can help in the incorporation of future advancements of technology, making this proposal future proof. In particular, this has been a huge point of stress for the EU, which must be able to set regulatory polls that can match and sustain the pace of innovation, without being an obstacle to it.

If these conditions are not met, the regulation proposal risks to become obsolete just years after its implementation, or even before it passes the various legislative phases, due its non-ability to keep up with the technological evolution, leading to a huge missed opportunity to a fairer, sustainable and trustworthy AI market in Europe.

To make possible this possibility of a future proof regulation, it has been crucial for the Commission to define clearly what it is meant with the concept of Artificial Intelligence. Indeed, setting the right perimeter of what is AI or not, it is fundamental for regulators to know what they must continuously monitor for the implementation of the regulation, as well as in understanding the future evolutions of the technology. Furthermore, this debate can have also an impact on many other aspects relative to the proposal and its idea of innovation and SMEs development.

However, as underlined throughout this work, the term AI is not easily definable, since its applications can take many forms and perform different functions. In particular, it can be applied to both physical goods as well as cloud-bases systems and it can be applied to different sectors of the economy.

Thus, this unclear condition makes it crucial to find a proper definition for the technological class, to define the right perimeter of action for the regulation and avoid other future challenges that can emerge for the improper categorization of this concept. A vague classification can lead

to doubts of what is AI or not, and may well create unnecessary regulatory burdens or exclude from the scope more riskier practices.

For example, a company that develops or utilize a system that it is defined as AI by the proposals, despite not posing much treat on fundamental rights, may create an extra not unnecessary burden on these organizations, while also going against the main goals of the proposal. Similarly, it can also lead to the exclusion of some class of technologies that are not identified as AI, but may generate the risks that are the main focus of the regulation, thus, leaving these unmitigated and going against the regulation in the first place.

In the end, the Commission settle with a particular definition of AI, which has not convinced all the stakeholders that will be involved with this new proposal. In particular, it decided to define an AI technology as "software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with" (European Commission, 2021a).

As underlined in the proposal, it is of particular importance Annex I, since it defines what systems may enter or not in the definition of AI. In particular, it lists what are the so-called AI techniques and approaches, by dividing them in 3 categories. The first 2 are centered around machine learning and logic/knowledge-based approaches, but the third category has raised some concerns from various stakeholders, especially the business community. Indeed, the regulation regards as an AI approach, thus, under the compliance and the conditions required by the proposal, also statistical and optimization approaches (European Commission, 2021b).

However, this categorization can be a bit stretched and may incorporate into the regulation some usage that are not directly compatible with the classic AI definition. Indeed, these kinds of techniques are used by different sector of the economy and are not characteristic just of AI systems. This could easily mean that a company which does not consider itself as an AI developer can be faced by the regulatory requirements of the AI act because it utilizes common statistical techniques inside their business. Furthermore, even if it is used directly as an AI system, some have debated that their potential threat is limited compared to other usages, especially considering that most of the times these tend to have an internal use and are less likely to touch directly the general public.

As underlined previously, the importance of finding a balanced definition is also important for maintaining a future proof approach for the regulation. Indeed, AI is not a static concept, but it is prone to evolve continuously thanks to the progress done through research and investments.

For example, the first chapter underlined how AI has evolved immensely from just 20 years ago and this process is still ongoing.

Having this in mind, European regulators know that to be able to reach the desired effects, it is necessary to keep up with the newest technological developments, which is even more fundamental in a sector that evolves with a much faster pace compared to more traditional ones. For this reason, the regulation leaves to the Commission the right to adjust and implement newer developments into Annex I to maintain an edge over the newer trends.

However, this last concept is a huge point of debate around the proposal. Indeed, many stakeholders believe that it is unlikely that the legislative pace of the Union, with all its decentralized mechanisms, is able to keep up with the technological advancements (Anitec-Assinform, 2022). As shown over the years, technology tend to evolve in such a rapid way compared to the past and changes all aspects of society at the same time. Furthermore, the developments of these technologies and how they work may have many times a great level of opacity and usually at the beginning are misunderstood by both the general public and regulators. In particular, the latter may have difficulties in anticipating the effects that these new technologies may have on society, in terms of generating risks for consumers and businesses, considering also that they may lack knowledge or expertise of such intricated topics as newer technological trends. Thus, it is fundamental to be able to sustain the pace of innovation that regulators are directly helped by experts of AI and its application.

For this reason, it is crucial the role that will have the European Artificial Intelligence Board, which will be formed mostly by technical staff that will make studies and recommendations for regulators at the Member state level. Hence, it must ensure that the regulatory level keeps up as much as possible with the newest AI developments in terms of new generated risks for the single market, its businesses and its consumers.

2.1.2 Proposal composition

Although it will be a point of focus in later section of this chapter, it is important to underline how this proposal has decided to set rules for AI applications. Specifically, this has been done in terms of a risk-based methodology, which the Commission believes is the best route possible for the proper setting of harmonized rules for AI application development, market placement, and use across Member States.

In particular, it wants to divide these applications in different levels of possible risk generated, setting different measures and conditions to follow. For instance, high-level risk AI systems "have to comply with a set of horizontal mandatory requirements for trustworthy AI and follow

conformity assessment procedures before those systems can be placed on the Union market"
(European Commission, 2021a).

In this sense, it is fundamental that this proposal is able to strike the right balance in terms of accountability and liability between developers and deployers. Indeed, many companies that use AI systems (especially smaller businesses, or less digitalized) may buy these systems from another business, which has generated over the years a B2B market for AI application and their development across the market.

This may lead to cases in which an AI application may be developed without much inherent biases in itself, but the dataset used by the deployer to train the systems may have some intrinsic bias that can pose risk to the market. At the same time, companies that do not have much technological abilities employ an AI application developed by another companies, which does possess any irregularities from the start, creating a flawed system to pose the responsibility mainly on the company deploying the system. Thus, it is fundamental to strike the right in terms of liability among developers and deployers.

To assure this, there is a strong necessity that it is clear what is the difference between these 2 categories. Furthermore, these actors must understand among themselves in which category they might fit and this is not something automatic in itself. In this sense, these must be assured that it is clear as possible by competent national authorities. However, this requires a high level of collaboration and competence that is not guaranteed. Thus, it may be a risky proposition, as with other areas of the regulation, to give much of this responsibility at national level, since the regulation success may rest on their shoulders.

In addition, the regulation also focuses on innovation and small-scale providers as important elements of the proposal and fundamental for the development of a European AI market. For example, to be able to ensure the perfect balance between the regulatory conditions and the development of the market, it endorses a program for the development of innovative AI solutions following the rules of the regulation. The main measure is the creation of various regulatory sandboxes. This topic will be the central focus in a section below of this chapter, but it is crucial to highlight here that the main aim of these sandboxes is to guarantee the development of SMEs and startups through the reduction of the new regulatory burdens for these actors for a limited period of time in a closely observed environment of a particular sector. However, as it will be noted later, it does not guarantee a partial liability removal as in other cases, instead companies that participate in these must be compliant to the totality of the regulation, thus, limiting their capacity of experimenting freely (Truby et. al, 2021).

Finally, a crucial point of the AI act proposal is on the ability that NRAs can have in raise penalties against companies that are proved to have infringed some of the rules of the regulation. These may vary between a fine of millions of euros (from 30 to 10) or a share of total worldwide revenue from the previous year (from 6% to 2%), whichever is higher for the company. At the same time, these measures have a different weight in terms of the severity of the infringement. For instance, the highest possible penalty (30 million or 6%) may be issued to companies that do not oblige with either article 5 or 10 of the regulation, which respectively state the prohibited models of AI application on the European market and the rules for training AI application with the proper data sets ensuring a correct representation of the European population and respecting data privacy and personal protection. Conversely, the other financial measures are set for infringements of any other article of the regulation (20 million euros or 4%) or the supply of incorrect, incomplete or misleading information to the NRAs after their request (10 million euros or 2%).

Although these format measures have been decided at European level, it is important to note that the final decision on infringements of the regulation by companies is made by the NRA for Artificial Intelligence, thus, giving a lot of power in Member States hands with all the problematics that this may represent. Indeed, the approach of each NRA to the regulation may well entail in a different strictness towards infringement protection and the penalty that may result, generating in this way a great discrepancy among Member States for how harsh they enforce these measures.

To conclude this section, it is also fundamental to underline that the proposal must be compliant with other existing Union legislation for sector in which AI systems are or may be used. In addition, it has to be integrated with already existing legislation of safety components for products, in particular the New Legislative Framework (NLF), listed in Annex II of the regulation. In this way, it wants to avoid any legislator duplication and reducing burdens on companies. As the proposal wants to reduce the impact that AI system can have on consumers, it also ensures the compliance of the proposal with the EU charter of Fundamental Rights as well as the Genera Data Protection Regulation (GDPR), being also consistent with the new proposal of the Commission of the DSA.

To sum up, the goals of all the actions endorsed by this proposal can be summarized as effort to "increase people's trust in AI, companies will gain in legal certainty and Member States will see no reason to take unilateral action that could fragment the single market" (European Commission 2021a). In the Commission opinion, this will ultimately benefit the whole single market, by supporting the development of "a fast-growing AI ecosystem of innovative services

and products embedding AI technology or stand-alone AI systems" (European Commission, 2021a) and leading to the realization of an increased digital autonomy of the European market from foreign suppliers.

In the next sections, it will be looked more in depth some key aspects of the proposal to really underline the impact that the proposal wants to have. In particular, these points of focus will be centered around the possible influence that they can have on innovation and small-scale businesses.

2.2 Concept of level of risk

As underlined in the previous section, the Commission has decided to focus its efforts on AI application firstly by outlining a definition for this contested concept, with all its challenges. Then, it decided to classify AI systems not in terms of characteristics they possess or the way they are developed, but instead on the possible risk that the various applications can pose to society and consumers in particular.

In this sense, the Commission has used this methodology to place clearly each AI application in each category, which have in themselves different conditions and restrictions on their use and place in the market for companies.

In the Commission's opinion, this measure will help also in maintaining a future vision of the possible advancements of AI technologies, making it easier to classify one technology in its most adequate category. Thus, it creates a system in which regulators are able to categorize the newest innovations, making the pace of regulation at the same level to the innovation process. However, as reported in the previous section, it entails that regulators must be able to categorize the newest applications and its possible applications, which requires a high knowledge of the application that they are trying to classify, which it is not in itself an automatic conclusion.

In the following lines, it will be analyzed the different level of risk by AI applications and technologies, showing how each category has been set and the potential benefits for this kind of classification.

The proposal divides AI application in 3 macro-categories depending on the risks that they may pose on society: unacceptable risk, high risk and minimal risk. As stated above, these risk categories imply different rules and conditions that have to be respected as compliant with the proposal in question.

Firstly, the AI applications that place unacceptable risks to society are prohibited by Title II (Article 5) of the regulation. This article covers both AI practices done by both companies and

public authorities that may infringe some fundamental right or value of the Union. In this regard, the EU charter of Fundamental Rights is regarded as the golden standard to respect by AI system, thus, limiting its improper use that may affect negatively citizens as a whole or a particular group of society.

Following these standards, the regulation bans all those practices that may affect people's decision and distort their behavior in an unconscious way, causing a physical or physiological harm. For instance, the use of AI system that has been programmed to target particular groups of people with some characteristics and feed them with particular news and information that will change or confirm some ideas or biases (echo-chamber), which in the bigger picture could influence enormously society's choices such as elections, referendums or in general societal ideas.

At the same time, there is also the prohibition of AI systems that may cause discrimination against particular groups of society based on their age, demographic or physical traits. Such practices can consist in the use of AI systems by public authorities or companies that discriminate against a particular demographic or race group in comparison to others, giving them an unfair disadvantage. An example can be a financial institution that uses an AI system to check financial backgrounds for people that ask for a loan or mortgage that tends to grant less financial help to a particular sub-group of society (e.g. minorities, women or people with disabilities).

In addition, the regulation prohibits the use of real-time biometric identification by public authorities, unless in expectational cases (e.g. terrorist threats or child disappearance). At the same time, Article 5 explicitly outlaws the use of AI system for the creation of a system of social scoring which could easily led to cases of discriminations against particular persons or groups of society. Such example can be the use of facial recognition and other AI technologies in China to implement a "Social Credit System" that can give different opportunities or disadvantages to people depending on how they "score" as citizens, especially in terms of credit and finance access for citizens (Liang, Das, Kostyuk and Hussain, 2018).

Thus, this use of AI applications is considered by the Commission as an unacceptable risk for society, meaning that their unregulated use on a daily-basis will certainly create conditions that will distort the concept of equal opportunities, leading to discrimination and distortion of people's behaviors and infringement of the European Charter of Fundamental Rights.

2.2.1 High-risk AI

The second classification made by the risk-based approach of this regulation is high risk AI systems. This can be regarded as the bulk of this regulation as the majority of the piece of legislation focuses on them by setting rules and condition to respect (e.g. ex-ante conformity assessment and creation of quality management system) for the proper placement of AI software and products that have such components on the European market. These have been designed to mitigate the potential risks of AI systems and avoid that they escalate into unacceptable risks to European society.

The proposal differentiates among high-risk AI systems into 2 categories: as a safety component of a product or as the product itself. Another important difference that is underlined in the piece of legislation is how past European legislation on products safety or on particular sectors, may avoid the need to have a third-party conformity assessment to the particular AI product.

In addition, Annex III of the regulation lists the AI systems that may be regarded as high-risk due to their use in some of the sectors cited. These have been defined as risks that have been already materialized in society or their possible negative impact on society has been already identified as possibly dangerous and harmful to citizens (European Commission, 2021a). Some of these include the use of AI system for the management of critical infrastructure (water, gas, heating and electricity), management of people for both training as well as business purposes, which may affect people's ability to secure a livelihood and impact career prospects, and the evaluation of credit score inside a financial institution database that may determine access to financial opportunities or essential services and may be influenced by an AI system trained with data influenced by some kind of biases that may affect those rights. These are just some examples of possible use of AI that have made society more functional, but that at the same time pose threats to people's security and well-being in different areas due to some malfunctions, mistakes in programming, use of non-complete databases and non-compliant with the newest technologies for cybersecurity.

Although Annex III lists some of the categories of AI systems applications that are considered high-risk, this is however still a limited number to those risks that have already been materialized. To keep the regulation as much up to date as possible, the Commission reserves its right to update the list of high-risk AI systems by applying its risk assessment methodology and looking at the specific purpose of potential new systems as well as its potential modalities of use. However, as noted above, this system relies a lot on the collaboration between NRAs and European regulators in communicating and identifying these newer practices, thus requiring a high level of technical competence. Furthermore, these application effect on society

are not identifiable immediately right away, but after time has passed (Smuha, 2021). This could easily lead to a scenario in which a new AI system is approved as compliant with the regulation, but after some time it leads to effects that were not predicted at the start.

As stated before, the categorization of AI applications as high risk entails in many requirements and conditions that all actors in the placement and usage on the market (developers, deployers and users) have to respect to ensure a proper compliance with the principles of this regulation proposal. These are a combination of both technical and legal standards that have to be maintained on the different stages of production and availability on the market.

Starting from technical requirements, the proposal requires high-risk AI applications to respect different requirements that are regarded essential as a way to mitigate the potential risks that they might pose to citizens' fundamental rights and overall safety.

These ranges in different aspects of AI systems working and their potential effects. For instance, the proposal requires that AI systems are trained with high quality datasets to avoid any potential discrimination and allowing AI systems to have as complete picture as possible of European society without any potential inequality embedded in the system. However, this seems a quite vague condition to follow and able to bypassed easily, since there are no clear objective criteria that must be followed to assure compliance. Furthermore, the conception of high-quality datasets that allow AI to represent society is also much debatable, since, as showed previously, the way in which data mediates reality may entail different conception of the quantitative representation of an intangible reality (Alaimo and Kallinikos, 2021; 2022). Thus, it is not a given conclusion that the use of this kind of datasets will ensure the mitigation of the risk underlined in this regulation.

At the same time, it is required to providers of high-risk AI system to provide different levels of information from their development phase and their performance throughout their lifecycle to guarantee their compliance with the regulation in so-called "logs". This information could compromise different categories such as general characteristics, the capability and limitation of the system, the process of data training and testing, as well as the process chosen for the risk management.

Another fundamental condition that the regulation poses on AI systems is their need to be as transparent as possible to consumers, making their outputs comprehensible and providing also a set of instructions on the possible proper use that can be achieved with the relevant system. This could also be problematic as well since most of the times the outputs are most of the times opaque or are difficult to comprehend by someone with a high level of knowledge. Furthermore, the base of AI systems is to evolve continuously as more information is provided to them, thus,

their outputs may evolve as well over time as they "learn" more and it is difficult for a developer to guarantee a level of transparency for results that are not expected at first.

In a similar fashion, the regulation obliges the need to set by developers of a proper system of human oversight for the working of the AI system, which should be set before being placed on the European market, allowing any risk of improper management of AI systems malfunctions. In addition, the regulation regards as essential the need of high-risk AI systems that must comply to an appropriate level of accuracy and robustness of its intended goals and its performance, as well as a strong system of cybersecurity put in place. The first concept means that the application developed should perform the intended purpose of its development in an accurate way, without going much off rail. On the other hand, the concept of robustness stands for the ability of the system to be "resilient against risks connected to the limitations of the systems as well as against malicious actions that may compromise the security of the AI system and result in harmful or otherwise undesirable behavior" (European Commission, 2021a). However, these 2 conditions are difficult to maintain since, as underlined above, AI systems are continuously evolving and, thus, they can easily produce an output that may not be expected at first by developers. If this functionality of AI applications is limited, it restricts all the technological class, by limiting all of its enormous potential.

Furthermore, the proposal requires developers to assure an appropriate level of cybersecurity of the system to avoid any potential exploitation of its vulnerabilities, which may lead for instance to risks of malfunction or infringements of users' privacy rights. This has been framed to comply with the whole GDPR, but the definition of appropriate level leaves a lot of room to national regulators to set what it is meant with this term with all its possible risks. Hence, it may lead to a situation in which different Member States may require more or less stringent standards among each other.

Finally, the proposed regulation requires AI systems defined as high-risk to be placed before an ex-ante conformity assessment during their production phase. The majority of these conformity assessment to both minimize the burden on the economy and regulators will be performed by the providers under their own responsibility. In this process, they have to guarantee the compliance of these AI systems with all the conditions of the AI act, as well as the compliance with the setting of a robust quality, risk management and monitoring system. In particular, this process is referred to those practices listed in Annex III, thus, called stand-alone high-risk AI systems. After this process has been completed, the provider should register system into an EU catalogue database to allow the oversight and supervision by competent authorities at both European and national level. On the other hand, those AI systems used as

safety components listed in Annex II will remain subject to conformity assessment practices of the relevant legislation, but with the addition of having an extra focus on the requirements of this regulation as well as the other sectorial ones.

As showed above, this conformity assessment procedure requires different standards to follow depending on where a product is classified in the regulation. Thus, it is fundamental that companies that are going to perform these are able to have a clear idea on how their product is identified. To do so, NRAs should provide questionnaire and information for AI providers and developers to understand this classification. However, this seems a lot of weight on the shoulder of NRAs, which it is not guaranteed to be able to comply to this challenge. If companies are left on their own, they could easily infringe the requirements of the proposal without knowing it, or must employ a consulting firm that may help them in this process, but this will ultimately increase even more the costs on these organizations.

In addition, the proposal expects that these AI systems, undergoing conformity assessment, should perform a new every time a change occurs to some key characteristics of the system or its intended purposes, thus, making the compliance with the regulation uncertain. Moreover, it requires also that systems that have a continuous learning algorithm, which are able to learn and adapt their function after being placed on the market, should be not allowed to have substantial modification to its purpose and functions from those identified by the provider during the conformity assessment. This is a particular debatable point since it is really unclear in itself. For example, what companies that provide customized solutions to clients, thus, having different purpose each time, should do? It is a complicated and costly process to perform a conformity assessment procedure each time a customized AI system is sold to a client.

Despite the majority of conformity assessment procedure are self-provided through internal control checks, those systems of biometric identification have to be subjected to a system of third-party conformity assessment assuring their regularity with the requirements of the regulation.

2.2.2 Low risk AI

After the analysis of high-risk AI systems, there are still 2 typologies of AI systems that have to comply to different and less strictly rules. The first typology of systems is formed by those that interface directly with people through a direct interaction, used to detect people emotions, usage of biometric data and creation or manipulation of content (so called deep fakes). In these cases, the regulation sets lower level of regulatory requirements needed to comply by systems,

but it requires that there should be a high level of transparency towards the people interacting with those systems.

Indeed, this is necessary to allow people to make more informed decisions and having a higher level of decision making through knowing that they are interacting with a machine and not another human. This is something especially revolutionary for those companies that nowadays use a system of bots for the management of customer care and relationships. However, it raises some the limited conditions placed on this type of technologies compared to high-risk ones, in particular, if are taken into consideration their potential to manipulate people's decisions and behavior, by using images and audio that deeply resemble reality. Indeed, this type of AI use can have extremely harmful consequences for people involved and society as a whole by spreading malicious and false information, as well as for theft and fraud (Yavuzkilic, Sengur, Akhtar and Siddique, 2021)

The second category is composed by those systems that pose low to none risks to the European market. In these cases, the regulation does not pose any condition or requirement to be respected for the free circulation around the single market. However, it suggests and encourages that those companies that develop low-risk AI systems to set own code of conduct mirroring some of the conditions written in this regulation, hopefully at business association level especially at sectorial areas. In this way, it hopes to create the condition for a decrease in fragmentation of regulation across sectors and companies and, most importantly, to guarantee the spread of a trustworthy AI at Union level, allowing the increase of AI adoption across businesses in the Union.

2.3 Regulatory Sandboxes

As underlined in the previous chapter, the EU is still far behind in the level of companies that are part of its AI market or deploy AI systems in their business, as well as in terms of investments provided by the national governments and the Union, compared to both US and China, which regarded as far ahead. To diminish this gap, the EU has identified its high level of expertise on this subject as a mean to improve innovation through the development of an AI strategy with investments in key areas that foster the development of AI (European Commission, 2020a). However, the regulatory constraints placed by this regulation on companies that develop or deploy AI systems may diminish the effect of this measure and could easily increase the gap between the EU and foreign markets, making the distance probably insurmountable.

To avoid this scenario, the Commission has inserted a somewhat new mechanism for the European regulatory framework to balance regulatory constraints and the natural progress of innovation. This section will focus in depth on the provisions laid out in Articles 53 to 55 that centers around a key new instrument that European regulators have started to incorporate in recent years, that is, regulatory sandboxes. This measure has been gaining steam across the regulators of states around the world as a way to both regulate newer technologies that are revolutionizing a particular sector and avoid any stoppage to the progress of innovation.

Indeed, an example of a sector in which this formula has seen a lot of success is the Fintech, which consists as the use of newer digital technologies in the financial sector. To keep up with the pace of innovation, many states have started to create this system to help regulatory compliance for companies that propose new technologies or services. At the same time, it is considered crucial also to ensure the balancing of these innovative services with the protection of citizens (consumers) rights moving forward.

This phenomenon for Fintech has started in the UK by the Financial Conduct Authority which decided to set up this first experiment to test possible innovative products for this sector, created by companies in the UK market. In particular, this measure was created as a way for these companies (primarily SMEs but also larger corporation) to test voluntarily their services in an environment with a limited liability and exemption from some regulatory constraints, as well as with a real customer basis.

In particular, the UK has endorsed 3 mechanisms that are regarded as sandboxes for the FinTech sector. The first one allows companies that want to test their products to have a restricted authorization that it not obliges companies to take the full authorization process, and helps them to have an advantage of time, while helping them in the end getting the authorization. The second type consists of the FCA giving guidance to firms on the regulatory requirements will apply to the specific new technology. Finally, it can grant more permissive conditions also called no enforcement action that gives more leeway in testing and experimenting for these companies.

The success of this measure in the UK has been both on the level of voluntary application by companies and the high level of approval to those application shown by the FCA. This in turn has led to the spread of this idea of regulatory measure around other countries, such as Australia and the Netherlands (Zetzsche et. al, 2018). For example, both Australia and the US have decided to create a similar measure in their regulatory system in the coming years for Fintech and, maybe, also other sectors.

In a similar fashion, regulatory sandboxes have started to gain steam also in the EU as a way to balance the regulatory constraints applied to critical sectors of the single market and the progress of innovation in that area. For example, the Bank of Italy has deployed in recent years a regulatory sandbox for FinTech companies within the Italian market, which it is currently gathering the requests for participation from the business side.

At the same time, it can be a way for the EU to protect the technological process, in face of a need of further consumers' protection, by helping especially European SMEs in this sector to safeguard their competitive power against bigger tech companies.

For this reason, there has been a lot of praise towards the implementation of such measure for the AI sector in which there are limited European companies (mostly start-ups and SMEs) in comparison to bigger foreign companies (especially Americans and Chinese). In this way, the Commission wants still to develop a framework for the protection of rights and the creation of a trustworthy AI ecosystem in Europe, while also allowing the progress of innovation without placing any obstacle to this process, in particular this is what is suggested in Article 53-55 or the AI regulation proposal.

Before looking in detail about the content of this articles for the provision and the European definition of this concept, it is first better to look closely more on what are regulatory sandboxes, how they work and what benefits may bring to both innovators and regulators.

Regulatory sandboxes in general terms can be defined as an environment in which innovators (mainly businesses) can test their new products with few regulatory constraints to respect, real customers and a continued guidance by regulators (Allen, 2019). This last point differentiates this measure with other types of regulatory exemptions, that is, the continued relationship that it originates between companies willing to bring an innovative product on the market and regulators placing rules for the well-being of consumers and the parity of the market.

It is also important to underline that firms that participates into regulatory sandbox will be exonerated just by few rules of the regulatory framework, not all the conditions present, and applied to the real customers, which will be still be protected by laws on customers protection. In addition, regulators participate in these regulatory sandboxes as a guiding figure for companies that want to test their innovative practices inside this protected environment, by explaining them the components and the need to comply to the regulation.

However, this relationship permits a bilateral exchange of knowledge and information. Indeed, the sandboxes provided to regulators the opportunity to learn how regulatory practices affects the innovatory ideas promoted by participants, while innovators may gain a more practical knowledge and understanding of the regulatory practices and goals.

In addition, it also helps regulators in acquiring newer information and knowledge about innovative technologies as well as business models, which may help their regulatory efforts through the understanding of the working and their possible effects, as well as their potential risks and challenges. However, an important barrier to the implementation of regulatory sandboxes is the need of high levels of resources, especially human ones, as well as a necessity of good knowledge of the technical inner working.

In the end, some have argued that regulatory sandboxes have an important role in encouraging entrepreneurship and innovation. This is possible thanks to the relationship that regulatory sandboxes create between regulators and innovators is the fundamental link that allows the reduce likelihood to place regulatory burdens on innovation, impeding its development process (Alaassar, Mention and Aas, 2020). Thus, they become a sharing forum for both parties to exchange knowledge about both regulatory practices and newer technologies understanding their potential impact on the market.

Furthermore, it is essential that the creation of these sandboxes assure that there is no obstacle posed by regulation that may impede market entry or generate loss of productivity, which will generate a huge loss for AI applications through discouraging their application and implementation across the single market.

Finally, the sandbox allows regulators to grasp in a more direct way the possible direction that a technology or application can have on consumers and fundamental rights, while also see what impact can the regulation have on the development of newer solutions. In this way, it enables them to modify or update the regulation to be more open to innovation without negatively affecting companies that apply to these measures.

2.3.1 Regulatory sandboxes within the AI act

Following this brief introduction on sandboxes, it will be now looked specifically at the concept of regulatory sandboxes applied to both AI applications and the proposal in particular, pointing out how this measure can be fundamental in balance regulation and innovation.

Article 53 essentially defines a regulatory sandbox applied to AI technologies as "a controlled environment that facilitates the development, testing and validation of innovative AI systems for a limited time before their placement on the market or putting into service pursuant to a specific plan" (European Commission, 2021a).

In addition, title V of the proposal envisions the need to create a regulatory framework that could still encourage innovation. To this end, it pushes the creation of AI centered regulatory

sandboxes at national level, which they should design also a framework for their governance and supervision.

These solutions shall facilitate the development and testing of innovative AI systems through an experimentational environment with real consumers, while also being under strict regulatory oversight to ensure the compliance to the main provisions of the proposal and other EU legislations before these systems are made available on the national market.

Furthermore, the proposal also envisions regulatory sandboxes as a mean to increase regulators knowledge of the newer technologies and its potential applications on the real world, while also helping SMEs and startups in being able to access the market, by removing their main obstacles. However, it is important to underline that, while the proposal believes that regulatory sandboxes are fundamental to safeguard innovation in face of a higher level of regulation, it does not oblige single Member States in setting up any sandboxes. Instead, it encourages the newly created national competent authorities to create freely regulatory sandboxes, with also their own basic framework for testing, as well as an ad-hoc system of governance, liability and supervision (European Commission, 2021a).

The Commission envisages just overtime the creation of common standards and rules between the European Artificial Intelligence Board and national competent authorities (Truby et. al, 2021) for the harmonization of the regulatory sandbox process across the Union.

Thus, the regulation foresees the responsibility for the creation and the running of these programs in the hands of national authorities, having in mind the principles and criteria that have been developed in cooperation with the European Artificial Intelligence Board in a fully cooperative environment. In turn, this will guarantee the creation and pursue of a common European approach to the development of this instrument.

However, the main problematic that remains is that these sandboxes are formed on a voluntary basis for Member States, which requires the setting of an ad-hoc body and use of deeply focused resources (physical and monetary) on monitoring and supporting innovators. If member states are not ready, this process could take time that could really undermine a lot of opportunities for companies that would like to participate to these projects. In addition, Member States could also create sandboxes that do not respect the standards set up by European regulator, thus, avoiding the main goal of the proposal. In turn, this could limit the scope of companies that can participate to this measure and limit in some way the innovation level across Member States.

Furthermore, the regulatory sandbox envisioned in the AI act proposal, unlike other types of regulatory sandboxes used for Fintech, gives to companies some exemptions to the conditions of the regulation, while also leaving them still liable completely liable in case of infringement

(Truby et. al, 2021). In addition, the regulation envisions that companies that participate in these sandboxes have still to comply with further protection of data privacy rights. This ultimately means that companies that are trying to innovate will still liable to the infringement of any legislation about data protection at both EU and national level, such as the GDPR. Thus, all of these conditions may make companies less encouraged to participate in these experiment areas, if they could still face the same constrictions that they would be placed under otherwise. In this way, there could be a high probability that it can create a situation in which business-oriented innovation may be slowed down totally by this proposal, unless something is changed.

The final chapter will go in depth on these last point by looking at how the innovation process may be directly affected by this regulation proposal, in terms of loss of steam and more costs and obstacles placed on innovators, thus, decreasing the chances of the European market to catch up with foreign ones. In particular, it will be looked at whether the measures of regulatory sandboxes as framed in the proposal can be effective in fostering innovation in face of increasing regulatory constraints on AI development.

2.4 Focus on SMEs and Startups

To conclude this chapter, it will be analyzed another fundamental aspect of this proposal, that is, the great centrality that small-scale providers and deployers (SMEs and Startups) must have to properly implement this regulatory framework.

In particular, these actors are regarded as crucial participants to the European market and fundamental to ensure the potential independence of the European AI ecosystem from foreign companies. To underline this point, both the proposal and other documents such as the White Paper on Artificial Intelligence of the European Commission believes that it must be a priority for both the EU and national governments to encourage small-scale providers in both developing and implementing AI solutions (European Commission, 2020a).

Indeed, these actors are the most fragile towards the various aspects of this technology, especially in terms of change. As highlighted in the previous chapter, they can revolutionize enormously their business model by implementing AI solution, towards an increased productivity and efficiency. However, they can also suffer more than other businesses the costs that these new technologies bring to their expenses for tasks such as data training, software costs and reskilling of workers.

The high level of initial expenses could be really damaging to small-scale providers, since they could have enormous initial losses on the return on investment before starting to invert the

trend. This aspect can be endured by large organizations that may have a long-term planification and a stock of resources that help endure this moment. On the other hand, smaller companies, that may be less capable to sustain such an economic impact, are more likely to be both discouraged or may interrupt their transformation in face of these problems.

Similarly, small-scale actors of the AI market face the same challenges. Indeed, the costs and lack of finances are their principal obstacle to growth and any possible change if not prepared by it could be fatal to their development.

For these reasons, both the EU and single Member states in their AI strategies have developed different strategies to help these actors to flourish in the AI market. It must be also noted that these have had some mixed result in fostering the development of an AI market. Indeed, despite having a high level of knowledges and expertise on the field, Europe and its member states still lack targeted investment to be able to untap this potential and be able to catch up the US and China, which have been the biggest investors in the development of an AI ecosystem within their countries (Brattberg, Csernatoni and Rugova, 2020). In particular, this prowess has powered an enormous level of startups creation over the years, which have made also possible the growth of this market and also its innovation level as global trendsetters.

In this sense, EU's small-scale companies do not find themselves in a similar situation. Many programs set at both European and National level still lack a strategic plan to help and facilitate the growth and creation of startups. Most of the times these do find themselves in a disadvantageous and uncompetitive position, making the overall European market as uncompetitive in face of bigger foreign players.

However, these measures must have a high level of success also to protect SMEs from larger organizations that may apply predatory practices that may impede their growth on the market, or could simply be able to buy them in face of the risk of running out of business. In this way, it will be created a situation in which there are just few companies (mostly foreign) that are the main players and (indirectly) rule-setters in the market.

Startups will likely suffer a similar faith, that is, after the development of an innovative product they could be just bought or become an affiliate to a larger company, due to the high unstainable costs of being on the market and their difficulties to find finances to bear these costs. In this sense, these plans are fundamental for the survival of a European market and for breaking the hegemony of many other bigger foreign companies.

Furthermore, many studies have shown that a high level of innovation inside markets are delivered by smaller companies, which generate a lot of plurality in the market and to be able to compete have to create innovative solutions. Indeed, they have been defined as

"entrepreneurial ventures pursuing profitability and growth through innovation practices" (Cavallo, Ghezzi and Rossi-Lamastra, 2021). These companies are centered around the concept of growth through innovation, making a fundamental output of their business. Thus, it is fundamental that Member States and, in particular, their governments envision and create programs that alleviates the burden on this type of businesses to let them contribute to the innovation process freely. Leaving unprotected SMEs and startups, thus, may well led to a total stagnation of the AI sector or, at least, a slow down on the process of technological advancements.

The EU has attempted just recently to facilitate the development of AI SMEs and startup, through a strategic program that fosters the growth overtime. The European White Paper on AI poses as a fundamental prerequisite that SMEs can access and use AI freely inside the European market and not being in a disadvantageous position compared to larger corporations. For this reason, it endorses the creation of Digital Innovation Hubs and AI-on-demand platform as main features of the Digital Europe programme endorsed by the Commission and Member States (European Commission, 2020a).

In particular, these hubs will be mainly programmed and performed at member states level as a way for SMEs to understand and adopt AI (European Commission, 2020a). In addition, the Commission encourages Member States to set a series of innovation hubs to allow, in this way, a specialization on each AI sub-topic and ensure a better implementation track by SMEs around Europe.

At the same time, the White Paper understands that the main impediment for the implementation of AI by SMEs is represented by finance and, for this reason, it has endorsed a pilot investment fund of 100 million euros for innovative developments in AI. InvestEU will also become a way to transfer these capitals to innovative SMEs in the field of AI.

Although these measures look as a promising start by the EU, the success of such programs relies heavily on Member States collaboration and their willingness to invest and participate willingly in this process. However, it is not a forgone conclusion that this will be the case, especially in terms of resources that are needed to endorse these programs. If this is the case, the gap between bigger companies that have more finances and small-scale providers may increase over the years.

For example, the Osservatorio Artificial Intelligence of the Politecnico di Milano (2022) reports that only 6% of the SMEs in Italy have started an AI project inside their business environment, which is in sharp contrast with bigger corporations (59%) that have undertaken at least one of these projects. Thus, there is still an enormous gap in Italy between SMEs and larger companies

in the implementation of AI systems in their business model. In particular, the 6% of SMEs is divided between a 4% for simple experiments and only 2% full-scale projects, underlining that there are still many challenges that impede the adoption of AI systems inside an SME environment.

To invert this trend, the Italian government has developed a strategy that follows the path drawn up by the EU in developing a system that can help SMEs to flourish in the AI market. For example, the Strategic Program of the Italian Government for 2022-2024 sponsor a plan formed by 24 policies that have as their main goals the strengthening of the AI sector in Italy (Italian Government, 2021). An important area of focus of this plan is the development of a strong framework for SMEs in their quest for adopting AI solutions inside their business environment. For instance, the plan endorses the development of over 20 Digital Innovation Hub promoted by Confindustria Italia with the goal of increase sensibility and awareness for small providers, provide technological evaluation of the SMEs products, offer strategic planification for AI adoption programs and employees formation. Thus, it has an important network that ensures that as much SMEs as possible can benefit of a technology and knowledge transfer to improve their business results through AI. However, there are still doubts that the governance systems developed for this program are capable to catch as most companies as possible, depending on the levels of resources allocated to it, as well as companies' willingness to participate.

2.4.1 SMEs and Startups protection within the AI act

As it will looked in depth in the next lines, this regulation proposes similar solutions for small-scale providers in allowing their development of AI solutions or AI powered business models, in a safe and trustworthy environment for all parties involved (companies and consumers). At the same time, it wants also to reduce the burden of the regulatory constraints of the proposal, while also ensuring the respect its requirements and conditions.

Indeed, it regards as fundamental to promote innovation that SMEs and startups that develop or use AI systems are highly considered. To do this, it encourages Member States in the development of targeted programs for raising awareness on the benefits of the regulation, as well as the advantages that it will bring a more regulated AI market for all parties involved.

It also specifies that Notified Bodies responsible for the conformity assessment shall consider the need of small-scale providers when setting fees. In this way, it wants to decrease the impact that these costs may have on these businesses and that may discourage the development or use of newer systems.

In addition, the proposal sustains that regulatory sandboxes set up at Member States level must give a privileged route to small-scale providers to allow for a greater level of experimentation and, thus, higher level of experimentation inside the European market, while also allowing for a greater plurality of small actors in Europe, instead of having just a few big corporations.

Despite the measures proposed in the regulation have as the main goal the maintenance of a plurality in the European market through the protection of SMEs, it still has flaws that may limit its potential positive impact for small-scale providers. As underlined above, SMEs are actors in the AI ecosystem that are most fragile to changes, being it economic shocks, external events and regulatory constraints. In this sense, studies tend to vary on the burden that these constrictions can provide on SMEs.

For example, the Center for Data Innovation estimates that compliance costs for an SME with a turnout around 10 million euros will be around 400 thousand euros for a high-risk AI system that requires a quality management system to be set (Mueller, 2021). However, these numbers are criticized as not based on the available numbers provided by the Commission studies (Renda, Laurer and Yeung, 2022), as well as wanting to demonstrate such situation as a common case, despite being a specific unlikely case (Haataja and Bryson, 2021). This shows how difficult it is to give a proper monetary impact on a proposal so groundbreaking and never seen before. Thus, these numbers can in some way help us capture in some way, how the proposal may well impact the way SMEs produce AI systems.

Thus, while the creation of spaces to try and innovate such as regulatory sandboxes are useful for small-scale providers, its attempts are still very limited and may pose even damages to these players. For instance, the need to comply to conformity assessment procedures by AI developers may seem as a way to protect and regulate the market. It can pose damages to small-scale developers of AI systems that in most cases relies on creation of tailored-made approaches towards customers, which also their advantage compared to bigger providers, that may be not approved in advance by conformity assessment (European Digital SME Alliance, 2022). In this way, their primary advantage over bigger companies may be lost, or can cause a slow of service, due to the need to pass under the conformity assessment procedure.

On the other hand, it may affect less bigger corporations that develop most of their product as a standardized product and, thus, may just need one conformity assessment procedure for their products, which affects also in proportion their finances as compared with small-scale providers.

Indeed, the AI regulation impact assessment developed by the European Commission (CEPS et.al, 2021) estimates that costs for obtaining a certification for an AI unit may cost to

companies on averages around 16,800-23,000 euros, which they consider as around 10% to 14% of development costs based on average system having a cost of 170,000 euros.

While these numbers are regarded by some studies as underestimated by disregarding additional costs of implementation like hiring a consultancy firms or new personnel to be sure to comply with the regulation which can skyrocket these expenses (European Digital SME Alliance, 2022). They still remain an enormous amount to be placed on companies, especially small-scale providers that on average may lack financing. Thus, this must be a great point of confrontation between regulators and Small-scale providers.

In addition to these constraints that may be faced by SMEs and startups, they could also risk that the positive actions proposed in the regulations may be remain just words on paper. Indeed, the actions proposed by the Commission on the proposals are rested on the shoulders of member states, which are encouraged to comply with these requirements on lifting some of the regulatory weight from small-scale actors and in helping them understanding the regulation and whether their products may infringe the requirements and conditions. In itself, this proposition seems flawed.

Indeed, the high power that Member States possess may lead to an improper completion of the goals encouraged by the Commission, due to either National Regulators unwillingness, as well as lack of funding that may limit the programs developed by national governments for small-scale providers.

It is fundamentally important that this collaboration is of high level and with a lot of effort at Member States, to allow for a proper implementation of the proposal, while also protecting SMEs interest and opportunities in the market.

For instance, the provision of information and the network created by Member States at national level are fundamental to mitigate the impact of the regulation and, at the same time, to assure compliance. In this sense, the primary reason for the infringement of regulations are due to an ignorance or an improper knowledge of the rules. Thus, it is fundamental that small-scale actors are helped and protected by Member States.

Similarly, Member States are fundamental, as also suggested by the Commission in the White Paper of AI (European Commission, 2020a), to finance and develop programs that help the spread of AI beyond the conditions set in the regulation proposal.

As pointed out by the Anitec-Assinform, a member of Confindustria Digitale representing ICT businesses, in its assessment of the regulation, the AI act can be an enormous opportunity for smaller player if it is included in a broader strategic design that also includes measures in favor of data access for systems training and investments in enabling infrastructure (Anitec-

Assinform, 2022). For example, it is fundamental that Member States provide shared data spaces with facilitated access for smaller companies could significantly enhance the value of the AI ecosystems. In this way, it will be a way to guarantee a complete and non-discriminatory access to high quality datasets that will improve the training and testing of newly created AI systems.

Furthermore, the proposal does seem to overlook also some of the problems that are leading to the underdevelopment of an AI market, especially for SMEs and startups. For example, the AI act does not encourage or underlines the importance of setting up programs to boost AI competences in each Member State. Indeed, if these are not available, small-scale companies may struggle to find competent personnel with the proper capacities to handle and program AI applications, especially with an increasing demand also from bigger companies with larger financial resources.

Thus, the creation of a regulatory framework without other supportive measures to avoid the increase of the gap between smaller and larger companies will not allow for the proper development of a European AI market.

The final chapter will go in depth on these topics by looking at how SMEs and startups may be directly affected by the regulation proposal, in terms of constraints put on them and whether this may overall negatively affect the European market. In particular, it will be looked at whether the proposal and its governance system at national level can really protect both SMEs and startups in face of increasing regulatory pressures.

Conclusion

To sum up, this chapter analyzed the AI act proposal of the European Commission, focusing on its main provisions. The regulation has as its main goal the creation of a more trustworthy and sustainable AI ecosystem, believing that this would help greatly the spread of this technology class across the European economy, while also protecting citizens fundamental rights.

To do so, it endorsed a risk-based methodology to classify AI systems in terms of their potential threat to European society, ranging from unacceptable to low risk. In particular, high-risk AI applications are the central focus of the provisions of these measures, by placing different constraints on their operations, such as a conformity assessment procedure, the setting up of a quality management system and a high-level of transparency towards consumers. Despite

seeming a reasonable way to guarantee the protection of fundamental rights, these conditions seem likely unrealistic and not applicable to the main benefits and advantages of AI systems. Businesses-powered innovation is also a main point focus of the regulation, by attempting to balance regulatory constraints and this natural process through the creation of regulatory sandboxes. Although this regulatory tool has had successes in the FinTech, these endorsed by the proposal looks not so much promising. Indeed, much of the responsibility is left in the hands of Member States, which are just encouraged to set such measure and do not face any obligation. Furthermore, as shown by the English example, a sandbox requires a high level of competence by national regulators and a huge level of expenses of resources to fully benefit from this practice.

Finally, the proposal also underlines SMEs and startups as actors that needs to be protected and helped directly in face of the new constraints set up by the regulation. However, there are still some doubts on whether these effort at European level can be able to avoid this, especially considering the difficulties that these small-scale providers are facing currently.

This chapter has been a mean to introduce the 2 main research questions of this work. Specifically, these are: can the regulatory sandboxes be able to safeguard the innovation process of the European AI market? Is the AI act endorsing a program capable to protect SMEs and startups from the increasing constraints put up by the proposal itself and the already existing challenges?

3 Research methodology

The questions posed in the previous chapter have introduced topics that can have some serious impacts on the European AI market, by both hindering its innovation process as well as slowing down the growth of small-scale actors (SMEs and startups) in this sector.

These questions are centered around the proposal's measure to protect innovation (regulatory sandboxes) and to ease the burden on SMEs and startups. Although it exists a significant literature on these issues, this research wants to dig deeper on these by trying to shed a light on possible problems that has not been yet identified by the current literature.

To achieve this, this research has gathered more insights and data on the impact that the AI act proposal can have on innovation and small-scale providers themselves. In particular, this has been done by collecting qualitative data on these topics by interviewing both experts and professionals in the field of AI.

To do so, there has been a focus on the EU in general, but focusing in particular on Italy. This is a very interesting case study, since it is one of the countries in Europe that suffers from enormous delays in its digital development. In addition, Italy has been also one of the last EU countries to develop an AI strategy and it is behind on the development of an environment for innovative solutions and SMEs and startups. Thus, it has been interesting to see what could be the impact of the proposal on a market that is already behind within EU standards.

The choices made for this research have been made to have a picture as complete as possible. In this sense, the respondents for the business side have been chosen to represent SMEs and startups that utilize AI technologies in different sectors. In this way, there would be a more to have a comprehensive as possible point of view, looking also at whether the proposal may different impacts across sectors.

To be able to complement the view from the business side, it was also interviewed a representative of the Italian business organizations for ICT companies within Confindustria Digitale (Anitec-Assinform). This has given the possibility to have a comprehensive view of the opinions and main critical points of the proposal from a business association that has a lot of interest for their representatives' impact within the AI Act framework.

Furthermore, there was also the possibility to interview some experts on topics of AI, innovation, as well as on AI overall strategies at national and European level. The choices have been focused on profiles that had a lot of experience on studying and analyzing these technologies and their possible effects on society. Furthermore, there has been also a great specificity on looking for those that also had a study on regulatory thematic, especially in terms

of AI and similar technology application. For this reason, there have been a mix of AI experts, within public administrations, Ministries (MISE), Regulatory Bodies (Garante per la protezione dei Dati Personali) as well as university professors and researchers.

To complete this research, interviews were conducted with both business representatives of SMEs and startups, as well AI experts, lasting around 30 minutes each and focusing on the main point of focus of this research. The interviews were based on a set of questions, but, as the conversation progressed, the focus shifted on new topics brought up during the exchanges.

Although the questionnaires were standardized as much as possible, there were also some specific questions for each actor category to obtain in this way more direct insights on a particular topic.

In particular, the questions were centered around 2 main pillars. Firstly, it was asked what are the current challenges for the AI market in Italy and Europe, while focusing especially on innovation and small-scale players. In a similar fashion, the following question was what both Europe and Italy are currently doing to solve these issues and whether these attempts have been enough in their opinion.

Then, it followed the second pillar of the interview on the AI act regulation proposal. As stated before, some of these questions were also slightly personalized for each respondent category.

A common question posed was what is their opinion on the current proposal, while also pointing out potential critical points. Specifically, it was inquired to business representatives what could be the principal effect on their business model, as well as what actions they are currently taking to solve these issues. Furthermore, it was enquired to the business representatives whether their personalized solutions can be impacted by the standardized framework of the proposal, which was a critical point already underlined in the public discussions. It was also asked whether they could see some impacts of the proposal that can affect their sector in particular. Finally, a point raised is whether the proposal could directly affect their innovation process.

On the other hand, the AI expert questions were centered on the main focus of the research. A first focus point were regulatory sandboxes. In particular, it was asked whether they believe these could be effective in protecting innovation, as well as their opinion on the governance system of these measures.

Then, it was inquired on what could be the overall impact of the leeway given to Member States in setting measures to protect SMEs and startups from the increased regulatory constraints of the proposal.

All categories of actors have been able to provide this research with a lot of valuable insights on the research questions, while also adding a more information on the main topics analyzed by the proposal.

Below it is possible to find a table with the description of respondents' characteristics.

ID	Company/Institution	Field of expertise
Startup representative	Mediterraneo Lab 4.0	CRM
AI expert	I-Com	AI regulation
SME representative	SurgiQ	e-Health
Business association representative	Anitec-Assinform	ICT market
AI expert	MISE	AI national strategy
Business representative	ISG Italy S.p.A	ICT Management Consulting
AI expert	PopAI	AI regulation
AI expert	SOGEI	AI strategic implementation
Regulator	Garante per la protezione dei Dati Personali	AI regulation

Table 1: Respondents description

In conclusion, the transcripts of the interviews then were analyzed to identify and interpret all interviewee statements and develop the main findings in the next chapter, as well as the possible implications.

4 Findings and final discussions

In this final chapter, it will be exposed and analyzed the main insights obtained during the interview process and try to capture what are the main findings for the thesis' research questions. Then, there would a brief discussion on these findings, underlining the main possible real implications. In conclusion, there would be also some proposal for both Europe and Italy on how to approach to the topic of regulating AI, while protecting innovation and small-scale actors.

4.1 Impact of the AI act proposal on Innovation

The first round of the interviews was centered on the role that the proposal can have on the innovation process for the AI market within Europe and, in particular, Italy.

To look more on this issue, the first part of the interview was centered around a discussion on the current situation of innovators, looking at what obstacle and challenges they have to currently face. Then, it was analyzed the framework of the proposal for this area, that is, regulatory sandboxes, looking at the problems of this measure and its possible applicability.

4.1.1 AI innovation prior to the AI act

By starting on the current challenges for innovators, all interviewees agreed that a major problem is the lack of competences in Europe, but especially in Italy. In particular, there is a shortage of 2 different kinds of competences: vertical (technical capabilities on AI applications) and horizontal (a general knowledge of how AI works and its benefits for society). Both of these have limited the takeover of this technology across sectors in Europe and Italy.

Specifically, the first typology can impede the reach of a critical mass for the development of an AI market, for instance, by limiting the possibility to find competent people and engineers capable to develop innovative ideas. In particular, Italy suffers from a lack of specialized competences, especially in terms of engineers, which could be in part solved with the development of more targeted educational programs.

On the whole, despite having high quality level of knowledge, there is at the same time just a limited number of professionals and researchers competent on technical issues. This has created many difficulties for the implementation of innovative ideas within the European market, since in many cases these do not find the competent people that are able to develop them and generate as much innovation as possible.

Similarly, horizontal competences can affect also the development of AI, by hindering the capability of those measures that aim to develop the ecosystem. For instance, many public authorities that want to regulate these matters may not possess the highest level of competences on the topic to be able to set programs to foster the development of an AI ecosystem, especially if there are just a few engineers compared to many legal experts. The limited knowledge on AI and its benefits could easily led to missing enormous opportunities for AI development by not knowing what consists AI and what should be the targeted investments for its development.

As pointed out by all respondents, these have contributed to a lack of a clear Italian Strategy for the development of AI, without a vision on what could be the strategic goals to reach through a roadmap. In particular, the general director of business organizations of ICT companies and the other AI experts have stated that this unclear program makes it more like a declaration of intents and less a feasible plan, without clear strategic goals to be reached through defined actions to boost innovation.

This could be a specific problem also at European level, since also all the legislation and the plan already present at EU level provide just non-specific guidance, leaving a lot of space for the definition of policies directly in the hands of Member States. However, this could bring a huge problem of fragmentation within the European market, since the institution of different plans at national level with various degree of planification will lead to disparities in the level of innovation throughout the Single Market.

For example, a crucial point that has been endorsed by the AI White Paper of the European Commission is the creation of Digital Innovation Hub. As stated before, these have the goal of stimulating and promoting the production system's demand for innovation, strengthening the level of knowledge and awareness with respect to the opportunities offered by digitalization. Although these measures have proven to be partially effective in boosting knowledge and spreading innovation across the Member States territory, the AI experts during the interviews have pointed out that this kind of measure is too much fragmented and do not work in a strategic and collaborative way between each other with clear specific common goals.

Furthermore, it is a similar problematic for the development of innovative technologies through research poles set up around Europe. Many agree that there is not a coordinated effort in their management and their working in spreading also possible innovative solutions. Thus, it leaves these measures as a whole much fragmented and not achieving as much as expected at the start. Thus, the current problems of the Italian AI ecosystem for innovation reside in the inability to set up a system of competences generator at both horizontal and vertical level to increase AI takeover. The interviewees suggest as means to do so the increase of educational programs at

university level around STEM disciplines, as well as general courses on AI in also non-STEM degrees to understand the potential benefits for society, thus, decreasing a possible hostility from society towards this technology. In addition, another possibility could be the creation of research hubs with a more coordinated network among these to have a better spread of competences both at national and European level.

4.1.2 Role of innovation within the AI act

After this general part on the current situation for innovators, the interviews shifted on what the AI act proposal could entail for the whole innovation and what could be its overall impact. As seen in the previous chapter, the principal measures concerning innovation in the AI act are regulatory sandboxes, which have been thought as a way to balance the impact of increased constraints while safeguarding the innovation process.

On the whole, the responses during the interview process have been mixed on the beneficial power of sandboxes in protecting the innovation process. However, a common point of agreement is that regulatory sandboxes should be mandatory in their creation at Member States level and this point should not be left as an optional.

This could create enormous problematics for the innovation process of the European AI market. Indeed, it may be naïve to hope that Member States will set spontaneously and immediately a measure that requires a lot of human and financial resources to develop and manage them, as well as a strategic vision in setting them, which is something that has been lacking, for instance, in Italy's approach to AI.

Furthermore, the proposal leaves its implementation and creation totally in the hands of Member States without any indication on standards to follow for their creation and way of working. As pointed out by the respondents, this could easily increase fragmentation for these measures in setting different standards and rules to follow across Europe.

For instance, all the respondents have underline how in this moment it is still not clear what will be the governance of such a measure at the national level and there are no signs that point towards a quick plan being drawn up. In addition, Italy has yet to identify which will be the NRA responsible to monitor the proposal and its compliance, as well as the functioning and working of the sandboxes. In particular it is not clear whether there will be a new body or it will fall under the competences of an already existing agency.

However, this is not a common sight at EU level. For example, Spain has started the creation of the European regulatory agency for AI, which will be fully operational by 2023 (Gallego, Martin and Robles, 2022). This would be in perfect timing with the proposal implementation,

which should be around 2024/2025, depending on the quickness of the European legislative process. This shows that Italy is already behind schedule in preparing for this regulation, underlining the lack of a strategic vision on the AI topic.

The business-side respondents (SMEs/startups and business association representative) also pointed out that the lack of competences across the Italian ecosystem may well impact the potential positive effects of regulatory sandboxes. For instance, national entities that will govern and manage these sandboxes are unlikely to possess the necessary skills, competences and knowledge to manage them, since they may not know entirely what they are trying to regulate (AI) and can have difficulties to identify their long-term consequences on society, especially for newer technologies. Indeed, most of these bodies are formed by legal experts and not engineers that may have more knowledge on this topic, especially if the competences are transferred to an already existing body, instead of an ad-hoc one.

A way to solve this issue could be an EU push to national competent bodies to update their knowledge and hire the right personnel for sandboxes management. However, this is an unlikely solution, since the proposal does not set a mandate to Member States in creating regulatory sandboxes, but it is just a suggestion. Thus, all respondents suggest to avoid these issues to have an ad-hoc body that has the demanding dedicated resources for the management and implementation of such program to allow the maintenance of the natural innovation process.

In addition, many respondents have suggested that Europe should press a lot in creating instruments that allow the working of sandboxes to have effects on the whole EU and not just at national level. By creating, for example, a European mechanism that allows the scaling up of AI innovative products, experimented through sandboxes, making them able to circulate around European countries. Furthermore, it is also desirable the creation of multi-country sandboxes across EU countries over the long-run.

In this sense, they have also suggested the creation of a common EU approach towards AI innovation with a defined strategic vision in both investments and not just regulatory framework, to reach in this way the critical mass needed for the development of the AI ecosystem, as well as having less fragmented measures across Member States.

Furthermore, a common vision also on sandboxes would make them at a common ground across Europe, by also making them more effective. In this sense, the respondents pointed out that the effectiveness of regulatory sandboxes lies on their ability to be sufficiently broad, if this does not happen they could easily become irrelevant in fostering innovation. Indeed, it is important to avoid the creation of too many divisions, but create broad sandboxes that are able to capture

as much the effects of AI as possible, considering also that they are a general-purpose technology.

In addition, AI experts stated how sandboxes can be effective if their goal is targeted and well defined, as well as their broadness in terms of technological applications, considering also that AI is not well-defined concept. However, they also underlined how they can become much useless if in the experimenting environment there are still the conditions close to the proposal's ones, since innovation is best achieved when rules within an ecosystem are loose and guarantee to experiment as much as possible. In this sense, member states in setting sandboxes must be able to find the right amount of proposal's conditions within sandboxes to permit the protection of consumers' rights, while allowing an experimentation area that guarantee freedom to test new products without fear of possible repercussions from NRAs.

Thus, it is also crucial that the EU helps to find a balance to avoid fragmentation between member states in finding this proportion, which will stop disparities and slowing down of innovation for an ecosystem which is already behind from foreign competitors.

On the opposite side, some respondents from both the business side and AI experts have also underlined how sandboxes can have enormous benefits on innovation, especially on the cultural aspects. For instance, it could create more trust around innovative products for consumers thanks to a regulated framework in place. It can also encourage innovators to pursue their ideas thanks to a protective system, by having another easier mean to test their innovative product if the right conditions are set.

On the whole, the respondents see regulatory sandboxes as an important opportunity to test and provide new innovative ideas with the European and national (Italy) AI ecosystem. However, the effectiveness of such measure lies in being mandatory, making the emergence of different ideas across Europe possible. In addition, it is necessary to have a more coordinated effort between Member States and the EU to avoid too strict conditions for sandboxes, as well as a targeted and strategic goal for these projects. Finally, it must require member states to set the proper management and governance system for sandboxes, to avoid any possible delay of implementation which could hamper an already backward AI ecosystem in terms of innovation, while also ensuring that the proper level of resources is used to guarantee the effectiveness of sandboxes.

Although it could help a lot the innovative process of the EU on AI, sandboxes should and are not enough. Indeed, this should not stop both Europe and Member States in investing more on increasing competences, which are the main obstacles for the spread of innovative ideas and may also impede the work of sandboxes. Indeed, there should be dedicated investments at

national level on the development of AI ecosystems, with the use of new resources for the creation of competences at both vertical and horizontal level.

4.2 Impact of the AI act proposal on SMEs and startups

The second round of the interviews was centered on the impact that the proposal can have on small-scale players (SMEs and startups) within the European and Italian AI market.

To look more on this issue, the first part was centered on the current situation of small-scale actors. Specifically, it wanted to look at what obstacle and challenges they have to currently face. Then, it analyzes the framework of the proposal on this topic, looking at what could be some critical issues as well as possible opportunities for businesses.

4.2.1 AI SMEs and startups prior to the AI act

By starting on the current challenges for SMEs and startups, respondents have highlighted different aspects that in some way or another have affected the growth and the work of these actors.

As for innovation, a commonly agreed point is that the current lack of competences has affected these actors in an enormous way. For example, it has brought difficulties in finding the competent personnel for the development of new solutions, thus, blocking innovative ideas at the earliest stages. Furthermore, the ones that possess the right competences may be poached by bigger companies that are able to more benefits and higher salary, leading to a skill concentration into big companies at the expenses of smaller ones.

As stated before, the lack of horizontal competences across the Italian ecosystem also limits the creation of targeted programs that may help SMEs and startups in this field, thus, hampering the development of an AI ecosystem.

Another important issue pointed out during the interview process, especially by business representatives, has been the many bureaucratic obstacles present in Italy. These may well impede the development of both SMEs and startups through an overall increase in costs, as well as time losses by following all passages of bureaucracy. This could be particularly harmful for startups that, usually are formed by just few people, need to have a deep knowledge of the system to comply with the intricated regulatory conditions and may lose time that could use to develop innovative solution.

There is also an agreement between the academic and the business world on the cultural effect that AI businesses are currently suffering in Italy. Indeed, most of the times the creation of an

informatic system is seen more as a cost rather than as an advantage, especially in managing data. This can be attributed to a total lack of awareness raised on the opportunities and benefits of AI to a business model. To invert this trend, it is important to create a practical culture for AI, by understanding its practical applications and importance, which may lead to a higher level of implementation. This can be done for example by showing companies of different sectors case studies of successful examples of AI implementation. In this, it is fundamental the help of business organizations, showing the benefits of AI through gathering data and developing projects that may help the needs of as much companies as possible. In turn, this could increase enormously the B2B opportunities for AI small scale providers in the market, by increasing the will of other companies to implement an AI system within their business model.

However, there are also issues in the digital infrastructure of both Europe and Italy that make difficult the work of SMEs and startups. A first type is the lack of adequate datasets for SMEs and startups. Indeed, despite today data is easy to retrieve, most of the publicly available ones are foreign. As pointed out by the representative of an e-health company, this is a lot problematic for the training of AI systems, since they could be prone to biases by learning characteristic and information that are valid for a specific territory but not for their own. This can be resolved with national datasets as broad as possible to avoid any possible regional bias (especially the case when most datasets used to train machines are foreign). A similar issue is the fragmentation of data management systems in Italy. This is particularly true for public entities, such as administrations and hospitals, which have not been integrated over the years, making the data gathering process very difficult, especially in applying AI solutions.

Thus, it is still difficult to access these high-quality data for small-scale providers, since more accurate and quality ones may be too costly for them. If these are not developed, they will still be dependent on foreign tech companies, impeding the maturity process of a European market for AI.

A specific problem related to startups that limits their growth within the Italian market is the limitation that they have in participating in the public tenders. For example, the condition of having a consistent past turnover may impede the participation of startup, which could limit a great business opportunity for their development. However, there have been an inversion to this trend, allowing the participation of startups inside consortia and also giving bonus points to these startups for the possibility of winning a part of the public tender. This could help those startups enter and may win a small percentage of the available funds of the tender.

Finally, small scale providers may suffer to some structural issues without much help from both Europe and Italy, until recently. For example, some respondents pointed out how SMEs and

startups cannot also be able to access to universities and other center of studies that could provide a lot of competences and make them more innovative. To solve this issue, it could be set some programs that help this communication between these actors, which will help for sure the development of opportunities for the providers. Similarly, it could be set programs that help startups in assure some financial help, since their own may be limited, to increase their capacity to invest on the development of innovative solutions.

Thus, SMEs and startups are currently facing different challenges that limit their development and the overall creation of a completely independent European AI ecosystem.

4.2.2 The impact of the AI act on SMEs and startups

After this general part on the current situation for SMEs and startups, the interviews shifted on what the AI act proposal could entail for them and what could be its overall impact.

All interviewees agree that it is important to defend fundamental rights of citizens for a more secure and trustworthy use of AI, but this should be balanced with a loose framework that allows companies to maintain their competitive power.

This is especially the case for SMEs and startups, which, as seen before, face already many difficulties within the Italian ecosystem. Further strict conditions may well limit their development, as well as their competitive power.

Similar to the topic of regulatory sandboxes, the conformity assessment procedure is left almost completely in the hands of Member states, with the EU Artificial Intelligence Board just setting standards to follow. For this reason, it is unclear today what will be the specific requirements for businesses that produce high-risk AI systems for their conformity assessment. In this sense, the business side respondents have underlined that they are developing risk matrix for data management to respond to the need of a conformity assessment, while also continuously monitoring the evolution of the proposal and the actions that will be taken at national level to implement it.

However, the hope of these respondents is that the proposal will not be strictly enforced at national level to avoid many unnecessary burdens on their work. Indeed, their main fear is that this could impact their primary competitive advantage, that is, the ability to provide customized solutions to client. In this sense, a strict enforcement may need this companies to go every time through a conformity assessment procedure, slowing down their business work. Furthermore, the rigid codification of the proposal goes against AI inner nature of constant change and evolution, thus, the need of a conformity assessment is a contrary to how AI really works.

For this reason, while it is important to have conformity assessment when there is a change to the type of service or of an AI solution, these must be kept looser if there are just modifications done for personalization reasons, without changing much of the final goal of the applications. In this moment, the proposal leaves this point unfortunately still much unclear in the overall sense. If this is not respected, there could be a huge loss of competitiveness for SMEs in face of bigger companies that have the access to more finances.

Obviously, the proposal will lead to spend more resources for pursuing the creation of an innovative product by, for example, lengthen development times and increase costs (something that may be already high in terms of finances for startups). However, these new expenses may also bring advantages to small scale companies. For example, a regulated market may bring more trust among potential users, giving an opportunity advantage to companies that comply to these measures. In this way, a strong and clear regulatory basis can become also a system of de-responsibility for deployers, giving more security to users that there would not be major problems for them.

In this sense, some respondents from the business side pointed out how the incorporation of the AI act into the ISO could be a way to comply to the requirements, while also providing a secure framework for final users. This is achieved by an official third party that certifies the company's compliance with the proposal through a system of periodic audits, controls and training of personnel to assure a high standard. Thus, this system of standardized norm can be an important competitive advantage by increasing trust on the business and it can surpass the costs that it will entail. However, as stated before, the not elevated level of finances may limit startups opportunities to participate to such programs and may create an important barrier to entry.

In this sense, some respondents pointed out that, if the proposal is costly to comply, it creates an enormous competitive advantage for those that are able to follow it thanks to a big entry barrier. This could be particularly problematic for startups, which tend to develop products that evolve quickly and goes against the stable nature of a norm.

Furthermore, some respondents from the business side pointed out how it may be more useful to understand AI impact on these sectors and their users, to have a regulation based on field experimentation as a foundation stone. This could also help companies in avoiding some external costs on consultancy and legal to comprehend the measures, by having already a viable example in place.

Finally, some AI experts pointed out how the proposal can help in raising awareness among people on the topic, but it probably could not help change the agenda on these issues, which is a similar situation for personal data protection with GDPR. In this approach, some businesses

could suffer a lot more the weight of newer regulatory constraints, as with the GDPR, without a sufficiently strong apparatus that sustain SMEs and startups.

In this sense, the proposal is very vague, by encouraging Member States to develop measures and programs for the protection of both SMEs and startups, without giving an overall guidance or a strategic plan in this sense.

In this sense, all respondents pointed out how it is necessary that both Europe and Member States support SMEs and startup that invest in developing innovate solutions for the European market. If this approach is not followed, it will ultimately undermine the attempts at EU level to match the gap with foreign competitors.

However, some respondents have pointed out how the proposal could also put new added on member states on creating new plans and investments for the development of the correlated needs for the development of a functioning AI ecosystem. In particular, this must be done through a collaborative and strategic partnership that aims to favor and protect the development of small-scale providers for the development of an AI European ecosystem.

The respondents also put forward during the interview some examples of such programs or actions for the development of the AI ecosystem by having a more comprehensive strategy to increase the opportunities for AI companies of small level. For example, they have proposed an increase in public investment for public level research on AI on targeted topics to increase knowledge. Similarly, the creation of strategic center that connects AI startups across both Italy and Europe to participate together inside tenders as well as Horizon projects. Another proposal has been the creation of a public investment fund that gives incentives to those companies that implement an AI system within their business model, by increasing the demand for these solutions. Finally, they have proposed a better fiscal system to help startups, allowing them in this way to concentrate more on innovating the AI market in Italy.

In conclusion, the interviews pointed out that, while it is important to defend fundamental rights protection for a more secure and trustworthy use of AI, does not have to do so with the use of too strict constraint for AI businesses, especially smaller ones, which in turn can undermine their competitive power. Probably, the best solution would be to improve the regulation as framed in this moment, by making it less stringent towards small scale actors. Furthermore, it may be the best route for the EU and Member States to listen directly to businesses to balance this framework and loose up the norms to maintain small businesses competitive power.

4.3 Implications

Our findings confirm the limited ability of the AI act proposal in protecting both innovation and small-scale players in face of increased regulatory constraints. At the same time, they have also pointed out how this proposal can have also a positive effect in raising awareness on the need of a clear AI strategy, while also creating a general sense of trust around the market, thus, generating more business opportunities for businesses that are able to comply.

However, these benefits are mostly limited by the shortcomings of the proposal. Indeed, the proposal does not find the right balance between regulatory constraints for consumers protection, while limiting the impact on the competitive power of small-scale players, who are the most affected by any sudden change in the regulatory framework. Instead, it leaves the majority of the responsibilities for this area in the hands of Member States in setting the proper, while setting mostly vague provisions on what they should do. This could create enormous problematics, if a Member States does not have a strategic vision on what are the current needs of these business and is able to set the proper system to protect the, by causing a fragmentation inside the EU, as well as loss of competitiveness of the European market.

Furthermore, the leeway given to Member States also for sandboxes may well fragment the innovation process inside Europe. Indeed, the non-mandatory nature of sandboxes inside the proposal are a huge risk for innovation in Europe. For example, it can lead to a scenario in which there is are increased constraints for small companies, without a free area that allows them to experiment new innovative solution. This could ultimately slow down the innovation process of both Member States and European AI market, while also damaging SMEs and startups business opportunities.

Moreover, the proposal should set also a clear system of governance, as well as indications on how they should operate, to help countries that do not have the competences to set such programs and avoid any possible division within EU. For instance, states readier to implement such measure thanks to a defined governance system and clearly defined strategic goals, may benefit more from such measure than other countries. Thus, it could easily create divisions within the European AI market.

In addition, our findings point out that the proposal, while being a good base for regulating the AI market, is not enough for the development of an AI ecosystem. Indeed, there are other structural problems that slow down the takeover of these application, which go behind a lack of trust by consumers.

In this sense, both the EU and Member States should set up a clear and strategic roadmap on what could be the investments and programs to solve these issues, especially the lack of

competences and digital infrastructures. These measures would also help AI takeover across society, which, in turn, will make the proposal implementation at national level easier and create a more secure AI ecosystem in Europe. These could also entail the creation of a strong network of common innovation centers at EU level, which will spread innovative ideas across the national territory boosting the overall innovation process.

In conclusion, our findings point out how the proposal is an important to raise awareness on AI in Europe, especially in terms of more security for citizens. However, the proposal must balance this without limiting small-scale players competitive power. Moreover, its measures for protecting innovation and small-scale actors should be more strategically defined at EU level, instead of giving carte blanche to Member States which could increase fragmentation inside the European AI market. Finally, the proposal would be more effective if it was integrated into a strategic plan for the development of the European AI ecosystem tackling its main structural flaws, especially in terms of competences and digital infrastructure. In turn, this will transform Europe into a competitive force and an important center for innovation on the global stage.

Conclusion

This research had the goal of identifying what could be the impact of the AI act proposal on the innovation process and small-scale actors within Europe. In this sense, despite having somewhat mixed results, the final point would be that, despite having good intentions for the development of the European AI ecosystem, the proposal results incomplete and must be integrated with a strong collaboration and a strategic plan both at the EU and Member States level to decrease the pitfalls of the legislation without posing any negative impact on innovation and small-scale players.

Indeed, the proposal has a good premise to create a regulatory framework for a technology that, together with its positive effects on efficiency, could bring negative effects on society if used in malicious and unsafe way.

However, it is not able to balance this premise with the creation of strict conditions on companies, which could be particularly detrimental for both SMEs and startups that most of the times do not possess such a strong basis as for larger companies, in terms of both understanding the new situation and also in financial terms.

Furthermore, the proposal endorses regulatory sandboxes as a mean to protect innovation in face of increasing regulatory constraints. Despite being a revolutionary measure within European regulatory culture, it is still limited in its nature. Indeed, it is a non-mandatory condition of the proposal, thus, leaving all the leeway to Member States in implementing them. In addition, it does not common standards to follow (it is auspicated in the future), but instead Member States will choose how to implement them and the conditions within these experiment areas. In turn, this could easily generate a lot of fragmentation within the European market. Finally, it is also questionable to believe that regulators could be capable to anticipate the long-term effects of newer AI technologies and products. Similarly, the proposal, despite posing many conditions on the production system of AI providers, does not entail clear measures to balance these for SMEs and startups, leaving all the power in the hands of Member states.

In this sense, Europe should place a central role in the implementation of this proposal to avoid exacerbating these issues and making the European market uncompetitive. Furthermore, it should also push a lot for reforms at national level that allow the emergence of more spread competences at Member States that are capable to spread innovative ideas, as well as more investments to create more connections between research centers and universities with small-scale actors, in order to allow for a more spread and awareness for this area.

In conclusion, the AI act regulation proposal could be extremely important in creating a more secure and trustworthy AI ecosystem within Europe, by protecting citizen's rights. However, it should balance more this with a looser conditions and requirements for businesses, especially small-scale ones (which are also the most present in Europe). Furthermore, the governance of the regulation implementation, especially for regulatory sandboxes and the protection of SMEs and startups, should have clearer and binding standards for Member States, with a higher level of participation from the EU. In this way, it will allow the safeguard of an already non-mature European AI market, avoiding a loss of competitive power in face of emerging global competitors.

Fortunately, the proposal in this moment is still under discussion by the European Parliament and it is at the early stages of the European legislative process. Furthermore, there has been a lot of pressure from business organizations and non-profit organization for the modification of this proposal, especially in setting looser conditions that will allow a safeguard of innovation and small-scale actors.

In this sense, it will also help the constantly increasing number of researches on this topic that, since it is still new, are going to emerge in the next years and could add a lot of new insights and considerations on some aspects of the regulation.

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Riassunto

Introduzione

L'Intelligenza Artificiale (AI) è una categoria di tecnologie e applicazioni che cercano di assomigliare il più possibile alle capacità cognitive umane. Negli ultimi anni, questa tecnologia si è andata diffondendo all'interno di ambienti e organizzazioni aziendali, con l'obiettivo di aumentare la produttività diminuendo i costi questo ha portato alcuni paesi a investire ingenti capitali nella ricerca su queste tecnologie e ad affrontare il problema della regolamentazione del loro utilizzo.

Tuttavia, questo fenomeno non ha avuto un andamento omogeneo in tutti i paesi del mondo. Ad esempio, l'Europa e i suoi Stati membri hanno accumulato un ritardo, in termini di investimenti e di produzione complessiva nel settore AI, nei confronti di Stati Uniti e Cina.

Gran parte di questo ritardo è dovuto ad un approccio disomogeneo a queste tecnologie e che non ha consentito ai Paesi dell'Unione di sfruttare il potenziale già presente, in termini di competenze e capacità produttiva portando di fatto uno svantaggio concorrenziale alle aziende europee rispetto a quelle degli altri paesi.

La difficoltà a trovare un'impostazione comune in Europa è stata anche dovuta ai timori generati dai rischi intrinsechi, per le persone e per le aziende, nell'utilizzo della AI, tra questi basti citare la gestione non corretta dei dati, i problemi connessi con l'etica degli algoritmi nonché alle pratiche di manipolazione da parte di questi sistemi.

Tuttavia, l'Unione Europea (UE) sta cercando di recuperare il tempo perduto. Nel mese di Aprile 2022 è stata pubblicata la relazione finale della Commissione speciale sull'intelligenza artificiale in un'era digitale (AIDA) nella quale viene definita la tabella di marcia dell'UE per l'AI. In questo documento viene notificato quanto l'Unione sia rimasta indietro nello sviluppo, nella ricerca e negli investimenti in campo di intelligenza artificiale e quanto l'intensificamento di un'azione dell'UE è fondamentale per la trasformazione digitale dell'UE poiché il suo impatto continuerà ad essere crescente sia sull'economia che nella vita quotidiana.

Per questo motivo l'Unione, ha stanziato diversi fondi per lo sviluppo di un ecosistema europeo di AI. Inoltre, ha anche spinto gli Stati membri ad agire a livello nazionale per creare le condizioni adeguate a tale sviluppo, attraverso la creazione di strategie nazionali di AI.

L'ultimo tentativo, in questa direzione, è stata la proposta di regolamento sull'AI pubblicata dalla Commissione Europea nel novembre 2021. La base di questa proposta è quella di stabilire regole chiaramente definite per un ecosistema europeo di AI e creare un ambiente più sicuro e

affidabile per i cittadini e le imprese, con l'obiettivo finale di aumentare l'implementazione di questa tecnologia all'interno del mercato unico europeo.

La presente ricerca vuole analizzare questa proposta esaminando quale potrebbe essere il possibile impatto di essa sulle le PMI e le startup, nonché sul processo di innovazione complessivo.

Capitolo 1: AI e il suo impatto sulle imprese

Questo capitolo introduce il contesto nel quale si svolge la ricerca introducendo il concetto di IA e i potenziali impatti sulle imprese.

Esistono numerose definizioni del concetto di IA in ragione delle molteplici declinazioni e applicazioni cui trova concretezza questa tecnologia.

In termini generali, l'IA può essere definita come "macchine che svolgono funzioni cognitive simili a quelle umane (ad esempio, imparare, capire, ragionare e interagire)" (Baruffaldi et al., 2020).

Diversi motivi hanno aiutato la diffusione dell'IA all'interno degli ambienti aziendali e ne hanno facilitato l'implementazione. In particolare, 4 sono considerati fattori cruciali.

Il primo riguarda la disponibilità aumentata di dati che consente ai sistemi di AI di lavorare in modo corretto e funzionale. Un secondo elemento è rappresentato dal miglioramento dell'infrastruttura di connettività, che ha reso le macchine capaci di interagire tra loro e di scambiare più rapidamente enormi quantità di dati. Un terzo sviluppo importante per la diffusione delle tecnologie AI è stato l'aumento della capacità delle macchine in termini di potenza computazionale. Un ultimo elemento importante è la mutata percezione e accettazione degli umani nei confronti dell'AI e nel suo utilizzo per migliorare le condizioni della vita di tutti i giorni e del lavoro nonché l'accresciuta diffusione delle conoscenze e competenze in questo campo.

Anche le aziende hanno di fatto compreso l'importanza dell'introduzione della AI nei processi produttivi, pertanto sfruttando le evoluzioni tecnologiche abilitanti precedentemente menzionate cercano di costruire una *road map* per implementare una strategia adeguata di introduzione dell'AI al loro interno in funzione delle loro caratteristiche dimensionali e dei loro mercati di riferimento.

Ad esempio l'uso ragionato dei dati è un elemento cruciale anche per creare un avvicinamento verso le aspettative dei clienti finali. Infatti oggi le aziende sfruttando le capacità d'interpretazione delle informazioni sullo stile di vita della popolazione riescono a finalizzare la propria produzione sulla creazione di prodotti personalizzati per le diverse categorie di

clienti. la stessa strategia applicata al mondo dei servizi, ha consentito, attraverso studi condotti utilizzando sistemi di AI, di migliorare i servizi ai clienti intercettandone le preferenze e le esigenze e di fatto fornendo una nuova categoria di esperienze più personalizzate per i clienti.

Allo stesso tempo, è altrettanto cruciale l'impatto che questa tecnologia può avere sul capitale umano di una determinata azienda. In questo senso, è fondamentale disporre di lavoratori che possiedano le competenze e conoscenze adeguate a collaborare in armonia con questa tecnologia. Questo obiettivo può essere raggiunto tramite un processo di formazione mirato che consenta alle risorse umane di comprende i vantaggi intrinsechi dell'uso di questa tecnologia e annulli i timori che naturalmente introduce un cambiamento così impattante.

un altro aspetto dell'utilizzo dell'AI in contesti produttivi è legato alla capacità di queste tecnologie applicate al controllo del funzionamento degli apparati produttivi di monitorare l'operatività delle apparecchiature in modo continuativo e di prevederne i comportamenti sulla base degli algortmi predittivi, creando un sistema di manutenzione preventiva delle macchine di produzione riducendo i costi di manutenzione e le risorse impiegate.

Le previsioni fatte dai sistemi di AI possono anche essere cruciali per analizzare se un determinato prodotto avrà successo o fallirà sul mercato, fornendo anche una previsione delle motivazioni risultato ipotizzato. Un altro esempio di utilizzo delle capacità dell'AI applicata al mondo produttivo è quella dell'uso di algoritmi di determinazione dei prezzi, che sono in grado di regolare i prezzi in modo autonomo anche in base domanda riscontrata o ipotizzata utilizzando algoritmi di simulazione.

Infine, è importante sottolineare che l'AI può avere un impatto maggiore in alcuni settori piuttosto che in altri. Ad esempio, quelli che tendono ad avere un rapporto più profondo e più stretto con il pubblico in generale sarebbero maggiormente impattati dall'uso di strumenti di AI rispetto ai settori che sono più esclusi socialmente.

Sebbene come sottolineato l'AI può portare enormi benefici nel modello di business di molte imprese, questa tecnologia può portare con sé anche alcuni aspetti problematici che hanno anche contribuito al basso livello di adozione di questa tecnologia in Europa rispetto a Cina e Stati Uniti tra cui: la scarsità di competenze tecniche, dai problemi connessi alla raccolta e gestione dei dati e alla *cyber security*, la necessità di investimenti più onerosi rispetto ad altre soluzioni meno performanti ma più tradizionali.

Ulteriore aspetto critico è la mancanza di una regolamentazione consolidata concernente i rischi e i danni anche di tipo etico che l'introduzione di questa tecnologia può introdurre nella vita degli esseri umani.

In questo contesto sono collocate due iniziative differenziate ma sinergiche la definizione e l'avviamento di un piano strategico per la diffusione dell'IA nella società e, soprattutto, tra le imprese da parte dell'Unione Europea e degli Stati membri, tra cui l'Italia; l'emanazione di atti regolamentari da parte dell'unione Europe finalizzati a disciplinare l'uso di tali tecnologie mitigando cosi rischi intrinsechi alla loro introduzione in numerosi aspetti della vita quotidiana.

Capitolo 2: La proposta di regolamentazione Europea AI Act

Nel rispondere ai rischi e alle problematiche segnalati nel capitolo precedente, la Commissione Europea ha sviluppato la proposta di regolamento dell'IA, abbreviato ad AI Act.

L'obiettivo generale di questa proposta è incoraggiare le persone e le aziende ad abbracciare i vantaggi dell'IA e a diventare attori abilitanti nel suo mercato in questo campo, sviluppando e implementando nuove soluzioni, promuovendo lo sviluppo di un mercato unico per un'IA sicura e affidabile, attraverso un approccio unificato in tutta l'Unione.

Nel fare ciò si vuole definire il concetto di IA in modo tale da creare chiare condizioni da rispettare nell'impiego e mantenendo però una flessibilità necessaria affinché le soluzioni adottate possano essere in grado di mantenersi valide anche di fronte alla naturale evoluzione tecnologica nel tempo. Però, come sottolineato precedentemente, la definizione dell'AI non è facilmente identificabile, poiché le sue applicazioni possono assumere molte forme e svolgere funzioni diverse.

Pertanto, questa grande diversificazione di ambito e di applicazione rende difficoltoso trovare una definizione adeguata del termine, per delimitare il giusto perimetro di azione per la regolamentazione ed evitare che la categorizzazione impropria di questo concetto vanifichi lo sforzo normativo attuale.

Tenendo questo in mente, i regolatori europei sanno che per poter raggiungere gli effetti desiderati, è necessario tenere in considerazione la velocità di evolutiva della tecnologia, il che è ancora più fondamentale in un settore che si evolve con un ritmo molto più veloce rispetto a quelli più tradizionali. Per questo motivo, il Regolamento introduce, nell'Allegato I, la possibilità per la Commissione di adattare e evolvere i meccanismi regolatori in funzione dell'evoluzione della tecnologia.

Tuttavia, quest'ultimo concetto è un grande punto di dibattito intorno alla proposta. Infatti, molte parti interessate ritengono improbabile che il ritmo legislativo dell'Unione, con tutti i suoi meccanismi decentralizzati, sia in grado di tenere il passo con i progressi tecnologici.

Guardando i contenuti della proposta, questa divide le applicazioni di AI in 3 macro-categorie a seconda dei rischi che possono comportare per la società: rischio inaccettabile, rischio elevato e rischio minimo. Queste categorie di rischio implicano regole e condizioni diverse che devono essere rispettate in quanto conformi alla proposta in questione.

Le applicazioni di AI che comportano rischi inaccettabili per la società sono vietate dal Titolo II (Articolo 5) del Regolamento.

La seconda classificazione effettuata è quella dei sistemi di AI ad alto rischio. Questa può essere considerata la parte più consistente di questo regolamento, in quanto la maggior parte della legislazione si concentra su di essi, stabilendo regole e condizioni da rispettare per il corretto posizionamento del software AI e dei prodotti che hanno tali componenti sul mercato europeo. Questi sono stati definiti come rischi che si sono già concretizzati nella società o il loro possibile impatto negativo sulla società è già stato identificato come possibilmente pericoloso e dannoso per i cittadini (Commissione Europea, 2021).

L'Allegato III del regolamento elenca i sistemi AI che possono essere considerati ad alto rischio a causa del loro utilizzo in alcuni dei settori citati. Per mantenere il regolamento il più possibile aggiornato, la Commissione si riserva il diritto di aggiornare l'elenco dei sistemi di intelligenza artificiale ad alto rischio, aspetto questo che introduce una possibile criticità legata alla necessità un alto livello di competenza tecnica e collaborazione con i singoli regolatori nazionali molto difficile da raggiungere nel breve termine.

Infine, la categorizzazione delle applicazioni di AI come ad alto rischio comporta numerosi requisiti e condizioni che gli utilizzatori devono rispettare per garantire un'adeguata conformità ai principi di questa proposta di regolamento. Si tratta di una combinazione di standard tecnici e legali che devono essere mantenuti nelle diverse fasi di produzione e disponibilità sul mercato.

Infine, la proposta definisce ancora due tipologie di sistemi di intelligenza artificiale che devono rispettare regole diverse e meno rigide. La prima tipologia di sistemi è costituita da quelli che si interfacciano direttamente con le persone attraverso un'interazione diretta, utilizzata per rilevare le emozioni delle persone, l'utilizzo di dati biometrici e la creazione o la manipolazione di contenuti (i cosiddetti deep fake). La seconda categoria è composta da quei sistemi che presentano rischi bassi o nulli per il mercato europeo. In questi casi, il regolamento non pone alcuna condizione o requisito da rispettare per la libera circolazione nel mercato unico, ma suggerisce e incoraggia le aziende a stabilire un proprio codice di condotta.

Dopo questa breve sintesi sui principali contenuti della proposta regolamentare, la ricerca si concentra sull'aspetto, previsto dal Regolamento, della protezione del processo innovativo. Per

garantire questo, la proposta tratta un nuovo strumento chiave che i regolatori europei hanno iniziato a incorporare negli ultimi anni, ossia le sandbox regolatorie.

L'articolo 53 della proposta di regolamento sull'AI definisce essenzialmente una sandbox regolatorie applicata a tali tecnologie come "un ambiente controllato che facilita lo sviluppo, il test e la convalida di sistemi AI innovativi per un periodo di tempo limitato prima della loro immissione sul mercato o della loro messa in servizio in base a un piano specifico" (Commissione Europea, 2021). Inoltre, la proposta prevede anche le sandbox regolatorie come mezzo per aumentare la conoscenza da parte dei regolatori delle nuove tecnologie e delle loro potenziali applicazioni nel mondo reale, aiutando anche le PMI e le startup ad accedere al mercato.

Tuttavia, è importante sottolineare che, sebbene la proposta ritenga che le sandbox siano fondamentali per salvaguardare l'innovazione a fronte di un livello di regolamentazione più elevato, non obbliga i singoli Stati membri a creare sandbox. Al contrario, incoraggia le autorità nazionali competenti sulla materia dell'AI che sono di nuova creazione a definire liberamente sandbox, con un proprio quadro di base per i test, nonché un sistema ad hoc di governance, responsabilità e supervisione (Commissione Europea, 2021).

Questa condizione può fortemente limitare l'impatto della sandboxes creando frammentazione fra le varie misure e i processi di innovazione fra gli Stati membri. Inoltre, gli Stati membri, vista l'eccessiva autonomia consentita, potrebbero creare sandbox che non rispettano gli standard stabiliti dal regolatore europeo, evitando così l'obiettivo principale della proposta.

Nonostante le misure proposte nel regolamento abbiano come obiettivo principale il mantenimento di una pluralità nel mercato europeo attraverso la protezione delle PMI e startups, esso presenta ancora dei difetti che possono limitare il suo potenziale impatto positivo per i fornitori di piccole dimensioni.

Il Regolamento lascia agli Stati membri molto spazio di manovra nel definire misure per limitare il peso dei vincoli normativi sugli attori di piccole dimensioni. Questo però può diventare un problema per il raggiungimento degli obiettivi della proposta.

Infatti, come sottolineato precedentemente, la mancanza di una visione strategica a livello nazionale può limitare i programmi di sviluppo e di aiuto per le aziende su piccola scala. Inoltre, la proposta sembra trascurare anche alcuni dei problemi che stanno portando al sottosviluppo del mercato dell'AI.

In conclusione, questo capitolo è stato un mezzo per introdurre le due principali domande di ricerca di questo lavoro: possono le sandbox regolatorie essere in grado di salvaguardare il processo di innovazione del mercato europeo dell'AI? Sta l'AI Act sostenendo un programma

in grado di proteggere le PMI e le startup dai crescenti vincoli posti dalla proposta stessa e dalle sfide già esistenti?

Capitolo 3: Metodologia di ricerca

Per rispondere alle domande di ricerca poste nel capitolo precedente, questa ricerca ha raccolto ulteriori approfondimenti e dati sull'impatto che la proposta di legge sull'AI può avere sull'innovazione e sui fornitori su piccola scala. In particolare, ciò è stato fatto raccogliendo dati qualitativi su questi argomenti, intervistando esperti e professionisti nel campo dell'AI concentrandosi sull'UE in generale, ma in particolare sull'Italia.

Nel complesso, le scelte di questa ricerca sono state fatte per avere un quadro il più completo possibile. Difatti, la scelta degli intervistati lato imprese è stata fatta per rappresentare le PMI e le startup che utilizzano le tecnologie AI in diversi settori.

Inoltre si è avuto l'opportunità di intervistare una rappresentante della business association Italiana per le aziende ICT all'interno di Confindustria Digitale (Anitec-Assinform) per avere una visione completa delle opinioni e dei principali punti critici della proposta da parte di un'associazione molto coinvolta sul tema della regolamentazione di tecnologie digitali.

C'è stata anche la possibilità di incontrare alcuni esperti sui temi dell'AI, dell'innovazione e delle strategie generali dell'AI a livello nazionale ed europeo con una grande esperienza nello studio e nell'analisi di queste tecnologie e dei loro possibili effetti sulla società.

Le interviste hanno avuto una durata media di circa 30 minuti ciascuna e incentrate sui punti principale di questa ricerca. Queste erano basate su una serie di domande, ma, man mano che la conversazione procedeva, l'attenzione si è spostata su nuovi argomenti emersi durante gli scambi.

In particolare, le domande erano incentrate su 2 pilastri principali. In primo luogo, è stato chiesto quali sono le sfide attuali per il mercato dell'AI in Italia e in Europa, concentrandosi in particolare sull'innovazione e sui piccoli operatori.

Poi, è seguito il secondo pilastro dell'intervista sulla proposta di regolamentazione dell'AI act, nello specifico sulle sandbox regolatorie e sulle misure per proteggere le PMI e le startup dai maggiori vincoli normativi della proposta.

In conclusione, le trascrizioni delle interviste sono state analizzate per identificare e interpretare tutte le dichiarazioni degli intervistati e sviluppare i risultati principali nel prossimo capitolo, nonché le possibili implicazioni.

Capitolo 4: Risultati e Discussioni finali

In questo capitolo finale, sono state analizzate le risposte ottenute durante le interviste, cogliendo quali sono stati i principali risultati applicabili alle domande di ricerca dell'elaborato. Come riportato precedentemente, la prima parte delle interviste è stata incentrata sull'impatto che la proposta può avere sul processo di innovazione per il mercato dell'AI in Europa e in Italia.

Partendo dalle sfide attuali per gli innovatori, tutti gli intervistati hanno concordato sul fatto che un problema importante è la mancanza di competenze. In particolare, queste vanno divise in 2 diversi tipi: verticali (capacità tecniche sulle applicazioni dell'AI) e orizzontali (una conoscenza generale del funzionamento dell'AI e dei suoi benefici per la società).

La mancanza della prima tipologia ostacola il raggiungimento di una massa critica per lo sviluppo del mercato dell'AI. Ad esempio la difficoltà di trovare persone competenti e ingegneri limita molto la capacità di sviluppare idee innovative. Allo stesso modo, la carenza delle competenze orizzontali può influenzare anche indirettamente la questione dell'AI, ostacolando lo sforzo di quelle misure strategiche a livello governativo che mirano a sviluppare l'ecosistema. Questo potrebbe essere un problema specifico anche a livello europeo, dal momento che i piani di diffusione dell'AI già presenti a livello UE forniscono solo una guida generica, lasciando molto spazio alla definizione delle politiche mirate direttamente nelle mani degli Stati membri.

Dopo questa parte sulla situazione attuale per gli innovatori, le interviste si sono spostate su ciò che la proposta di legge sull'AI potrebbe comportare per l'intera innovazione e quale potrebbe essere il suo impatto.

Nel complesso, le risposte durante le interviste sono state contrastanti sul potere benefico delle sandbox nel proteggere il processo di innovazione. Tuttavia, un punto comune di accordo è che la creazione di sandbox regolatorie dovrebbe essere obbligatoria per gli Stati membri e non dovrebbe essere lasciato come misura opzionale. In effetti, è difficile credere che gli Stati membri istituiscano spontaneamente e immediatamente una misura che richiede molte risorse per essere sviluppate e gestite, nonché una visione strategica nella loro definizione.

Questi segnali sono già visibili. Difatti, tutti gli intervistati hanno sottolineato come in questo momento non sia ancora chiaro quale sarà la governance di tale misura a livello nazionale e non ci sono segnali che indichino l'elaborazione di un piano rapido.

Per risolvere questi problemi, gli intervistati hanno suggerito la creazione di un approccio comune dell'UE verso l'innovazione dell'AI con una visione strategica definita sia negli investimenti che nel quadro normativo, per raggiungere in questo modo la massa critica necessaria per lo sviluppo dell'ecosistema dell'AI, oltre ad avere misure meno frammentate tra

gli Stati membri. Inoltre, una visione comune anche sulle sandbox le renderebbe simili in tutta Europa, rendendole anche più efficaci.

La seconda parte delle interviste è stata incentrata sull'impatto che la proposta può avere sui piccoli attori (PMI e startup) all'interno del mercato europeo e italiano dell'AI.

Partendo dalle sfide attuali per le PMI e le startup, gli intervistati hanno evidenziato diversi aspetti che in un modo o nell'altro hanno influenzato la crescita e il lavoro di questi attori. Un punto comunemente condiviso è che l'attuale mancanza di competenze ha colpito questi attori in modo enorme. Un'altra questione importante evidenziata durante il processo di intervista, soprattutto dai rappresentanti delle imprese, è stata quella dei numerosi ostacoli burocratici presenti in Italia. Questi possono ostacolare lo sviluppo sia delle PMI che delle startup attraverso un aumento generale dei costi, oltre a un appesantimento dei processi legati all'eccessiva burocrazia. Infine, è stato sottolineato come l'ecosistema corrente soffre di enormi problemi strutturali come la mancanza di adeguate infrastrutture digitali e problemi culturali sulla necessità di sviluppare e utilizzare soluzioni AI.

Dopo questa parte generale, le interviste si sono spostate su ciò che la proposta di legge sull'AI potrebbe comportare per loro e quale potrebbe essere il suo impatto complessivo.

Tutti gli intervistati concordano sull'importanza di difendere i diritti fondamentali dei cittadini per un uso più sicuro e affidabile dell'IA, ma questo deve essere bilanciato con un quadro di regolazione non rigido che permetta alle PMI e startups di preservare il loro potere competitivo. Per esempio, la procedura di valutazione della conformità è lasciata quasi completamente nelle mani degli Stati membri, con l'European AI Board che si limita a definire gli standard da seguire. Per questo motivo, oggi non è chiaro quali saranno i requisiti specifici per le aziende che producono sistemi AI ad alto rischio. Tuttavia, la speranza degli intervistati è che la proposta non venga applicata rigorosamente a livello nazionale, per evitare molti pesanti oneri sul loro lavoro degli attori su piccola scala.

Allo stesso tempo, le nuove condizioni possono anche portare vantaggi alle aziende di piccole dimensioni. Ad esempio, un mercato regolamentato può creare maggiore fiducia tra i potenziali utenti, offrendo un vantaggio alle aziende che rispettano queste misure. In questo senso, alcuni intervistati del settore commerciale hanno sottolineato come l'incorporazione della legge sull'AI nelle normative tecniche ISO potrebbe essere un modo per soddisfare i requisiti, fornendo al contempo un quadro sicuro per gli utenti finali.

In ogni caso, la proposta sul tema delle piccole realtà è molto vaga, in quanto incoraggia gli Stati membri a sviluppare misure e programmi per la loro protezione, senza fornire una guida generale o un piano strategico.

In questo senso, tutti gli intervistati hanno sottolineato come sia necessario che sia l'Europa che gli Stati membri sostengano le PMI e le startup che investono nello sviluppo di soluzioni innovative per il mercato europeo. Se non si segue questo approccio, si rischia di compromettere i tentativi a livello europeo di colmare il divario con i concorrenti stranieri.

Dopo aver descritto i principali risultati delle interviste, la ricerca si è focalizzata nel descrivere le possibili implicazioni di questi. I risultati confermano la limitata capacità della proposta di legge sull'AI di proteggere sia l'innovazione che i piccoli operatori di fronte all'aumento dei vincoli normativi.

Al contrario, l'AI act lascia la definizione della maggior parte delle responsabilità di quest'area nelle mani degli Stati Membri, stabilendo al contempo disposizioni per lo più vaghe su ciò che dovrebbero fare. Questo potrebbe creare enormi problemi, se c'è una visione strategica a livello nazionale su quali siano le esigenze attuali di queste aziende e non si è in grado di stabilire un sistema adeguato per proteggerle, causando una frammentazione e una perdita di competitività del mercato europeo.

Inoltre, il margine di manovra concesso agli Stati membri anche per le sandbox potrebbe frammentare il processo di innovazione all'interno dell'Europa. Infatti, la natura non obbligatoria delle sandbox all'interno della proposta rappresenta un rischio enorme per l'innovazione in Europa.

Inoltre, la proposta non stabilisce neanche un chiaro sistema di governance, nonché indicazioni su come dovrebbero operare, per aiutare i Paesi che non hanno le competenze per impostare tali programmi ed evitare qualsiasi possibile divisione all'interno dell'UE.

Infine, i risultati evidenziano che la proposta, pur essendo una buona base per la regolamentazione del mercato dell'AI, non è sufficiente per lo sviluppo di un ecosistema dell'IA. Infatti, ci sono altri problemi strutturali che rallentano l'adozione di queste applicazioni, che vanno oltre alla mancanza di fiducia da parte dei consumatori. In questo senso, sia l'UE che gli Stati membri dovrebbero definire una tabella di marcia chiara e strategica su quali potrebbero essere gli investimenti e i programmi per risolvere questi problemi, soprattutto la mancanza di competenze e di infrastrutture digitali.

Conclusione

In conclusione, questa ricerca aveva l'obiettivo di identificare quali potrebbero essere gli impatti della proposta di legge AI Act sul processo di innovazione e sugli attori su piccola scala in Europa. In questo senso, il risultato finale è che, nonostante le buone intenzioni per lo sviluppo dell'ecosistema europeo dell'IA, la proposta deve essere integrata con una forte collaborazione

e un piano strategico sia a livello dell'UE che degli Stati membri per ridurre le insidie della legislazione senza avere un impatto negativo sull'innovazione e sugli attori su piccola scala.

Per esempio, la proposta sostiene le sandbox regolamentari come mezzo per proteggere l'innovazione di fronte ai crescenti vincoli normativi. Nonostante sia una misura rivoluzionaria nella cultura normativa europea, la sua natura è ancora limitata. Infatti, si tratta di una condizione non obbligatoria della proposta, che lascia quindi agli Stati membri tutto il margine di manovra per la sua attuazione. Allo stesso modo, la proposta non prevede misure chiare per limitare i vincoli normativi per le PMI e le startup, lasciando tutto il potere nelle mani degli Stati membri.

In questo senso, l'Europa dovrebbe assumere un ruolo centrale nell'attuazione di questa proposta spingendo molto per riforme a livello nazionale che permettano l'emergere di competenze più diffuse negli Stati membri in grado di diffondere idee innovative, così come maggiori investimenti per creare più connessioni tra centri di ricerca e università con attori su piccola scala, al fine di consentire una maggiore diffusione e consapevolezza per questo settore.